

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave blank)

2. REPORT DATE
2 April 2001

3. REPORT TYPE AND DATES COVERED
JULY 2000 TO JULY 2001

4. TITLE AND SUBTITLE
AN ANALYSIS OF MEDICATION ERRORS AT A MILITARY MEDICAL CENTER: IMPLICATION FOR A SYSTEMS APPROACH FOR ERROR REDUCTION

5. FUNDING NUMBERS

6. AUTHOR(S)
Col KATHERINE SCHEIRMAN

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
WILFORD HALL, 59TH MED WING/ADR
LACKLAND AFB, TX

8. PERFORMING ORGANIZATION
REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
US Army Medical Department Center and School
BLDG 2841 MCCS-HFB (Army-Baylor Program in Healthcare Administration)
3151 Scott Road, Suite 1411
Fort Sam Houston, TX 78234-6135

10. SPONSORING / MONITORING
AGENCY REPORT NUMBER

33-01

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution is unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 words)

An analysis was accomplished of all inpatient medication errors at a military academic medical center during the year 2000, based on the causes of medication errors as described by current research in the field. The results of this analysis, which showed errors most often associated with information systems deficits and with the ordering process, were used as a framework for prioritizing elements of the current system which offer opportunities for significant error reduction. This framework, when combined with a detailed examination of the current inpatient medication processes, a review of recommendations on error reduction from the literature, and an investigation into the currently available information technologies, was used to develop a prioritized plan of action to address the root causes of reported inpatient medication errors at this medical center. The results of the analysis and the recommended actions to address systemic causes of errors were presented to the executive leadership for conceptual validation and future resource allocation decisions.

20040226 190

14. SUBJECT TERMS

15. NUMBER OF PAGES
87

16. PRICE CODE

17. SECURITY CLASSIFICATION
OF REPORT
N/A

18. SECURITY CLASSIFICATION
OF THIS PAGE
N/A

19. SECURITY CLASSIFICATION
OF ABSTRACT
N/A

20. LIMITATION OF ABSTRACT
UL

Running head: MEDICATION ERRORS

An Analysis of Medication Errors at a Military Medical Center: Implications for a Systems
Approach for Error Reduction

Col Katherine Scheirman

U.S. Army-Baylor Graduate Program in Health Care Administration

Graduate Management Project

2 April 2001

DISTRIBUTION STATEMENT A
Approved for Public Release
Distribution Unlimited

Acknowledgements

I would like to thank the many people who were of particular assistance to me in this project. Major Joe Mirrow and Colonel Thomas Peters provided encouragement and guidance. Dr. Sandra Barnes, Jackie Reeves, R.N., and Ms. Carol Biggs of the Audie L. Murphy Memorial Veterans Hospital guided me through the outstanding medication system at their hospital, and provided numerous forms which can be adapted for use by other facilities. Special thanks go to all the exceptional people at the medical center I studied, especially the Risk Manager, the Chief Nurse Executive, the Chief and Assistant Chief of the Medical Staff, the Chief of the Inpatient Pharmacy, the Chief of Information Systems, the Chief of Medical Records, and the innumerable clinicians who gave freely of their time and expertise in the interest of improving safety for their patients.

Abstract

An analysis was accomplished of all inpatient medication errors at a military academic medical center during the year 2000, based on the causes of medication errors as described by current research in the field. The results of this analysis, which showed errors most often associated with information systems deficits and with the ordering process, were used as a framework for prioritizing elements of the current system which offer opportunities for significant error reduction. This framework, when combined with a detailed examination of the current inpatient medication processes, a review of recommendations on error reduction from the literature, and an investigation into the currently available information technologies, was used to develop a prioritized plan of action to address the root causes of reported inpatient medication errors at this medical center. The results of the analysis and the recommended actions to address systemic causes of errors were presented to the executive leadership for conceptual validation and future resource allocation decisions.

Table of Contents

	Page
1. List of Tables.....	6
2. List of Figures.....	7
3. Introduction.....	8
Conditions which prompted the study.....	8
Statement of Problem/Question.....	9
Literature Review	9
Purpose	26
4. Method and Procedures.....	27
5. Results.....	30
Results of Medication Error Data.....	30
Results of Analysis of Current Medication Processes.....	39
The VA Medication System.....	43
6. Discussion.....	45
Medication Error Data	45
Current Medication Processes.....	47
Limitations of Study.....	49
Barriers to Implementation.....	50
7. Conclusions.....	51
8. Recommendations.....	53
9. Reference List.....	59
10. Appendices.....	65

Appendix A. Glossary of Acronyms

Appendix B. Incident Report Data Figures

Appendix C. Medications included in "Miscellaneous" Class

Appendix D. Medication Process Flow Charts

Appendix E. Example of Problems in Handwritten Orders

Appendix F. Veterans Administration Incident Report Form

Appendix G. Recommendations Matrix

List of Tables

	Page
Table 1. Medication Errors Reported by Unit	31
Table 2. Medication Errors by non-ICU Units, Adjusted for Occupied Bed Days.....	32
Table 3. Class of Medication involved in Reported Errors.....	33
Table 4. Types of Reported Medication Errors.....	34
Table 5. Processes in which Reported Errors Occurred.....	35
Table 6. Management Factors in Reported Errors.....	36
Table 7. Medication Factors in Reported Errors.....	36
Table 8. Times of Reported Medication Errors.....	37
Table 9. Patient Harm Determined From Incident Reports.....	38

List of Figures

	Page
Figure B1 Medication Errors Reported by Unit.....	66
Figure B2. Calculation of Goodness-of-Fit Test for Medication Errors by non-ICU Units, Adjusted for Occupied Bed Days for calendar year 2000.....	67
Figure B3. Class of Medication involved in Reported Errors	68
Figure B4. Types of Reported Medication Errors.....	69
Figure B5. Processes in which Reported Errors Occurred.....	70
Figure B6. Management Factors in Reported Errors.....	71
Figure B7. Times of Reported Medication Errors.....	72
Figure B8. End User of the Medication System.....	73
Figure B9. Actions Taken as a Result of Medication Error.....	74
Figure B10. Additional Actions Taken as a Result of Medication Error.....	75
Figure D1. Provider Order Process.....	77
Figure D2. Nursing Order Process.....	78
Figure D3. Nursing Medication Administration Process.....	79
Figure D4. Nursing Assessment and Documentation Process.....	80
Figure D5. Pharmacy Process I.....	81
Figure D6. Pharmacy Process II.....	82
Figure E.. Two examples of poor handwriting and confusing orders.....	83
Figure F. Veterans Administration Incident Report Form.....	84
Figure G. Recommendation Matrices.....	85

An Analysis of Medication Errors at a Military Medical Center: Implications for a Systems

Approach for Error Reduction

Introduction

Conditions which prompted the study

When the Institute of Medicine (IOM) report "To Err is Human," was released in November 1999, the American public was shocked by its account of the large numbers of patients injured, some fatally, by the medical care system in the United States. (Kohn, Corrigan, & Donaldson, 2000). This report extrapolated the data from two prior studies, which resulted in an estimate of the number of patients killed by medical errors in the U.S. to be between 44,000 and 98,000 per year. The results of the Harvard Medical Practice Study, which reported an adverse event rate of 3.7% of hospitalizations, 13.6% of which resulted in death, were first published in 1991 (Brennan, Leape, & Laird, 1991). The second study, published in the spring of 2000, found an adverse event rate of 2.9% in hospitals in Colorado and Utah, and reported that 8.8% of these adverse events resulted in death of the patient (Thomas et al., 2000). The high error rates, as well as an apparent lack of improvement over the previous decade, caused an outcry, and demands for action, from the political leadership as well as the public and the media. Costs associated with these medical errors were found to be high in financial terms as well as in the immense toll in human life and suffering; one study estimated a cost of almost \$4700 per preventable adverse drug event in a teaching hospital (Bates et al., 1997). Total national costs were estimated to be between \$17 billion and \$29 billion annually; direct health care costs comprise over one-half of the total (Kohn, Corrigan, & Donaldson, 2000).

Many studies of medical errors have focused on adverse drug events and medication errors because they are quite common, they affect relatively large numbers of patients, and they

account for significant increases in healthcare costs (Kohn, Corrigan, & Donaldson, 2000). Other reasons for the large quantity of research on medication errors include the possibility of error prevention and the increasing potential for morbidity and mortality as the use of pharmaceuticals continues to grow rapidly (Kohn, Corrigan, & Donaldson, 2000). Until quite recently, however, the medical literature has been deficient in studies on the causes of human error in medicine (Leape, 1994b). Most studies have focused on the errors made by nurses or pharmacists, but few have evaluated errors throughout the entire medication process (ordering, transcribing, dispensing and administering of medications). However, an extensive body of work from the cognitive psychology and human factors literature is beginning to be applied in medical errors research. The implications of this work, the antithesis of the prevailing medical model of blaming and punishing individuals for errors, have been successfully applied in other high-risk industries such as aviation and nuclear power. This systems approach to error reduction, although not yet widely adopted in medicine, appears to hold great promise for reduction of medication errors in the increasingly complex healthcare system.

Statement of the problem/question

This study will attempt to determine the relative contributions of various system factors which appear to be the root causes ("latent defects") underlying the errors that occur in the inpatient medication system processes (ordering, transcribing, dispensing and administering medications) at a military medical center, as reflected in CY 2000 incident reports.

Literature Review

Although a very high degree of public and political interest in the subject of medical errors was sparked by the IOM report, many practicing healthcare professionals were surprised by the report. Many believed that the medical care system in the United States was by far the best in the

world, and this report of death and injury was quite shocking. The emerging body of research over the past decade on human factors, error causation and system design had gone almost unnoticed by many health care professionals, as very little was published in the medical literature in this field. However, the practice of medicine in the United States has evolved from a cottage industry to one of the most technologically and organizationally complex in the world over the last 50 years (Sultz & Young, 1999). The amount of information on drugs that must be processed on a daily basis by healthcare providers and organizations has rapidly exceeded the capabilities of human memory and practice logistics (Schiff, 1999). The pharmaceutical companies develop, and the Food and Drug Administration approves, new medications at an ever-increasing rate. Three drugs (terfenadine, mibefradil, and bromfenac) were taken off the market within the last year because prescribers could not be relied on to follow critical guidelines for safe prescribing (Schiff, 1999). Despite the growing need for readily available information in all aspects of the medication process, health care organizations have failed to adopt the systems approach used so successfully by the aviation and other high-risk industries to increase safety in complex systems (Leape, 1994a). In fact, the current system, which depends on reliance on memory and handwritten orders, has become an anachronism that must be changed to bring it in line with the critical information requirements of the 21st century.

Definitions

Before beginning an in-depth discussion of medication errors, definitions of the relationship between medication errors, adverse drug events (ADEs), potential ADEs, and preventable ADEs are required. An adverse drug event (ADE) is an injury related to the use of a drug (Leape, 1994b). ADEs may range from trivial (a mild allergic reaction) to fatal. ADEs may be known complications of an appropriately used drug, an unforeseeable (unpreventable) allergic

reaction, or the result of an error. Those caused by errors are by definition preventable. A potential ADE is an error that has the capacity to cause injury but fails to do so, either as a result of good luck or because it is intercepted before reaching the patient (Leape, 1994b). A medication error is any error in the process of prescribing, dispensing, or administering of a drug, whether an adverse event occurs or not. This is often referred to as a breach of one of the “five rights” of the medication process – the right patient, right medication, right dose, right time, and right route. Many medication errors are trivial, and the majority do not result in patient injury. However, all potential ADEs and all preventable ADEs are the result of medication errors (Leape, 1994b). A list of all acronyms used in this report is found at Appendix A.

Medication errors

The initial, landmark research upon which the error estimates in the Institute of Medicine report were based, the Harvard Medical Practice Study, was published in 1991 (Brennan, Leape, & Laird, 1991). In this study, adverse events occurred in 3.7 percent of the hospitalizations, and 27.6 percent of the adverse events were due to negligence. Drug complications were the most common type of adverse event, accounting for 19 percent of the adverse events (Leape et al., 1991). Bates et al. (1995) published the first research which approached medication errors from a systems perspective. In that study, 247 ADEs and 194 potential ADEs were identified at two major teaching hospitals over a 6-month period. Extrapolated event rates were 6.5 ADEs and 5.5 potential ADEs per 100 nonobstetrical admissions. Of all ADEs, 1% were fatal (none preventable), 12% life-threatening, 30% serious, and 57% significant. Overall, 28% of all events were judged preventable, but of the life-threatening and serious ADEs, 42% were preventable (Bates et al., 1995). Errors that resulted in preventable ADEs occurred most often during ordering (56%) and administration (34%) (Bates et al., 1995).

Another more recent study of 4108 admissions at the same two prestigious tertiary care hospitals found that adverse drug events occurred in almost 2% of all admissions. (Bates et al., 1997). Of these adverse drug events, 60 of 190 (32%) were judged to be preventable, and the increase in length of stay attributable to the preventable adverse events averaged 4.6 days, with an additional cost of \$5857 per event (Bates et al., 1997). In 1998, a meta-analysis of four studies conducted from 1966 to 1996 found a rate of serious adverse drug reactions, defined as resulting in hospitalization or permanent disability, of 6.7% of hospitalized patients (Lazarou, Pomenanz, & Corey, 1998). The rate of fatal reactions was 0.32% of all inpatients, making these reactions between the fourth and sixth leading cause of death in the U.S. (Lazarou, Pomenanz, & Corey, 1998).

Even higher rates of preventable adverse drug events have been shown in ICU patients and in the pediatric age group. Rates of preventable adverse drug events and potential adverse drug events were shown to be twice as high (1.9 events per 1000 patient days) in the ICU setting as in a general medical or surgical unit; however, after correcting for the number of medications administered, no significant differences were found (Cullen et al., 1997). Pediatric patients, and particularly pediatric ICU patients, have been found to have error rates as high as 1 in 6.8 admissions, with a frequency of iatrogenic injury due to medication errors of one injury per 33 admissions (Kohn, Corrigan, & Donaldson, 2000). Clearly, significant opportunities for reduction in medication errors have been well documented in the literature.

Traditionally, the medical profession has focused on individual responsibility and blame for errors (Bates & Gawande, 2000). The professions of medicine, nursing, and pharmacy have developed a culture in which blame, reprisal, and punishment of the "wrongdoer" are used to attempt to prevent errors, and in which errors and mistakes are hidden from view (Berwick &

Leape, 1999). Contributing to this culture of secrecy and fear are the threat of medical malpractice litigation and the belief that errors by physicians, nurses and pharmacists are evidence of negligence or a failure of character (Leape, 1994a). This culture is based on the "perfectibility" model, which uses training and punishment to try to achieve a goal of perfection (Leape, 1994a). Any deviation from this perfection is "someone's fault," to be discovered through incident reports, and the cause attributed to a lack of proper training or, even worse, a lack of caring (Casarett & Helms, 1999). This approach is now felt by most researchers into medical errors to be inadequate to deal with the complex systems of the 21st century medical environment (Bates & Gawande, 2000).

In contrast, research in human factors and cognitive psychology in regard to human error, successfully applied to reduction in errors in aviation, manufacturing and the space program, is based on the belief that errors will always occur in complex systems. Human factors research is largely concerned with man-machine interfaces, and cognitive psychology has developed an extensive body of work into the causes of mental errors (Leape, 1994a). Based on this extensive research, which is now beginning to be applied to the medical profession, it is possible to predict when and how errors will occur, and design work environments to minimize those errors. In a groundbreaking study, Leape et al. built on this work from other fields; his group found that system factors were implicated in approximately three-fourths of all adverse drug events (Leape et al., 1995). In order to better understand this systems approach to error reduction, it is necessary to have an appreciation of the fundamental principles of human error from the research in cognitive psychology.

Mechanisms of human cognition that result in errors

Cognitive theory describes three types of mental functioning. The first is the automatic,

rapid, largely unconscious mental processing that enables a person to drive a car or perform other routine tasks with little mental effort. This type of mental process is termed "skill-based" activity, and it is controlled by stored patterns of pre-programmed instructions (Leape, 1994a). The second type of mental functioning, termed "rule-based" activity, occurs when a person confronts a familiar problem, for which the stored rule "if X, then Y" is sufficient. This pattern is much slower, and it requires conscious thought and effort. The third type of cognitive functioning is termed "knowledge-based." It occurs when a person confronts a novel situation in which stored knowledge must be accessed and the new situation then analyzed in light of the stored information. This process is even slower and much more laborious than rule-based processing. Mental functioning at this level can be sustained for only limited periods of time (Leape, 1994a).

Cognitive errors can be classified into two groups, based on whether the errors occur in activities that are skill-based or rule- or knowledge-based. Errors in skill-based activities are termed slips, while those that occur during rule- or knowledge-based functioning are called mistakes (Leape, 1994a). Slips can be classified into (1) capture, in which a more frequently used pattern takes over for a less familiar one, (2) description errors, in which the right action is performed on the wrong object, (3) loss of activation, a temporary memory lapse, and (4) association activation errors, which result from incorrect mental association of ideas (Leape, 1994a). An example of capture would be a trip in which the first part is a familiar route, such as one's daily commute, but, instead of changing the route to get to the correct location, one continues to drive to work. A descriptive error example would be spraying deodorant on one's hair instead of hair spray. Walking into a room and forgetting why is a classic example of loss of activation. An example of an association activation error would be answering the telephone when

a doorbell rings. Physiological and psychological factors, such as fatigue, boredom, fear, anxiety, or illness often contribute to the occurrence of slips. Interruptions and distractions are also frequent causes of these types of errors (Leape, 1994a).

Rule-based errors result in mistakes, on the other hand, when an incorrect rule is applied, either because of a misperception of the situation or because of a misapplication of a frequently used rule (Leape, 1994a). Mistakes caused by knowledge-based errors, in situations where no pre-programmed solution is available, occur either because of a lack of knowledge or because of a misunderstanding of the problem. Many of the mental processes that lead to errors, although incompletely understood, involve incorrect pattern matching (Leape, 1994a). Decisions are usually based on memory, which is less difficult than calculation or "looking something up." Biased memory, the overgeneralization and overregularization of the commonplace, occurs because familiar patterns are assumed to have wider applicability than they actually do (Leape, 1994a). Memory can also be biased toward a disproportionate emphasis on unusual events, weighing recent exceptions far too heavily in relation to actual statistical significance (Leape, 1994a). Other mechanisms for knowledge-based errors include the availability heuristic (the tendency to use the first information that comes to mind), confirmation bias (the tendency to look for data which supports one's hypothesis while ignoring that which contradicts it), and overconfidence (the tendency to believe in one's chosen course of action, even in the face of contradictory evidence) (Leape, 1994a).

Physiological and psychological factors that contribute to skill-based errors also influence rule- and knowledge-based processes. In addition, under stress errors in all processes may increase by several well-recognized mechanisms (Leape, 1994a). Coning of attention occurs when a single source of information is used in an emergency situation, such as when a pilot

focuses all his attention on the altimeter while ignoring the rapidly approaching ground.

Reversion under stress occurs when a recently learned behavior is replaced by a more familiar one under stressful conditions, even when it is inappropriate (Leape, 1994a).

A significant lesson learned from the cognitive theorists is that mental functioning in humans is a complex activity that is prone to errors, which will inevitably occur. This research into the mechanisms of human cognition that result in errors, along with the observation that all humans err every day, has contributed to the awareness that human errors are often brought about by systems failures, those characteristics of work or the workplace that make errors more likely (Reason, 2000). A further examination of the systems approach as it relates to error prevention is therefore needed.

Systems theory: latent errors versus active errors

Reason (1997) has called the systems failures that predispose to errors “latent errors”, which he terms “accidents waiting to happen.” In contrast, active errors are the mistakes whose effects are felt immediately, and which are often attributable to a single person. Latent errors are faults in design, maintenance, training, and management that “set people up” to make mistakes (Reason, 1997). While an operator error may be the proximal “cause” of the accident, the root causes have often been present in the system for a long time. Thus, poor design, faulty maintenance, or erroneous management decisions produce a situation in which a minor operator error or equipment failure can result in a serious accident. These systems design flaws create the “accidents waiting to happen” (Reason, 1997).

Yet another basic tenet of systems theory holds that the performance of a system is a property of that system, and that if a system is stable, that performance will be predictable. Thus, error rates are predictable properties of systems, or, in other words, “every system is perfectly

designed to achieve exactly the results that it gets" (Berwick, 1998). The logical conclusion is that in order to get different results, a system change is necessary; exhortations to "be more careful" will not lead to reduction in error rates.

This systems approach also explains why similar errors occur repeatedly in organizations, without regard to who happens to be the "operator" (or end-user) of the system at any particular moment in time. This observation is particularly relevant to medication errors, which tend to occur in similar ways throughout the entire healthcare industry.

To summarize the differences between the traditional approach to error within the medical professions, and the emerging approach based on systems theory, Reason (2000) states:

Two approaches to the problem of human fallibility exist: the person and the system approaches. The person approach focuses on the errors of individuals, blaming them for forgetfulness, inattention, or moral weakness. The system approach concentrates on the conditions under which individuals work and tries to build defences (sic) to avert errors or mitigate their effects.

Thus, human errors, rather than being causes, can be seen as consequences of upstream workplace and organizational factors (Reason, 1997). The identification of the human error becomes only the first step in an investigation into the root cause of the accident or injury. Yet another way of conceptualizing the difference between root causes and the human error phenomenon is an analogy to mosquitoes. The human errors (mosquitoes) can be swatted one by one, but they will continue to return until the swamp where they breed (the latent defects in the system) is drained. This view of error holds the promise of improving safety significantly throughout an organization. An exploration of the research in defenses against errors builds on this foundation.

Defenses

The multiple causes of error, the complexity of the systems involved, and the physiological and psychological factors related to errors mean that design of systems to reduce those errors is a difficult and challenging task. Development of a safe process requires attention to every detail in the design of the system: planning, construction, maintenance, training, allocation of resources and development of operating procedures (Leape, 1994a). System designs that make errors less likely or impossible are the most effective, as they reduce the likelihood of errors by a variety of end-users of that system, such as nurses, pharmacists, and physicians (Leape, 1994a).

The first line of defense involves making it easy to do things correctly, and very difficult or impossible to do them wrong. As an example, pre-filled syringes in the correct dosages are much easier to use than drawing up a dose from a vial, and much less error-prone. Another aspect of the first line of defense involves simplification whenever possible, as the chance of an error increases exponentially with the number of steps in a process (Berwick, 1998). For example, in a process with ten steps, each of which has a chance of an error of only .01, the chance of any error occurring in the process is 1 in 10. Reducing the number of steps is a more effective strategy in decreasing the overall error rate for a process than is reducing the probability of error at each step. Another frequent type of error, omissions, can often be reduced by a properly designed reminder system, or by redesign such that a process cannot proceed if an omission occurs (Reason, 1997).

The second line of defense involves making errors readily apparent when they do occur (Berwick, 1998). One of the problems with complex systems is that, when things go wrong, the operator of the system may not recognize the error. Ideally, systems design should plan for errors and make them visible, by alarms or other mechanisms, so that the human operator can remedy

the error in time to prevent harm to the patient. An example of this type of system would be a computer order-entry system that prevents an order for a medication overdose from being filled, and alerts the pharmacist to the error (Bates et al., 1998).

Thirdly, if the first two lines of defense fail, the system should be designed to allow reversal or recovery from an error that actually reaches the patient (Berwick, 1998). Once error rates are reduced significantly, recovery from errors becomes more difficult to achieve as personnel become less familiar with dealing with errors. Training and simulation, such as training in response to a patient with anaphylactic shock, become increasingly important, as does the requirement to have everything easily accessible to treat anaphylaxis close at hand. In a similar vein, equipment failures should be planned so that the equipment defaults to the least hazardous mode in the event of failure. An example would be IV tubing, which should default to a cutoff of flow, not to free-flowing mode (Berwick, 1998).

Many tactics are available to make the system changes required to support these three lines of defense. Nolan (2000) groups these tactics into five categories: (1) Reduce complexity (2) Optimize information processing (3) Automate wisely (4) Use constraints, and (5) Mitigate the unwanted side effects of change. These tactics will be explored later in more detail as they relate specifically to medication errors. Let us turn our attention now to the barriers that exist to implementation of the system changes that are needed for effective error and injury prevention.

Barriers

Changing the culture of an entire organization is an immense endeavor. A consistent finding from organizational behavior research is that organizations and their members resist change (Robbins, 1998). As previously stated, medicine has evolved in the 20th century from a cottage industry into a practice now dominated to a large extent by technologically and

organizationally complex institutions. However, many of the thought and behavior patterns established in the early days of the medical professions have been slow to keep pace with these technological and organizational changes. In particular, the belief that caring and competent professionals should never make mistakes persists despite a large body of scientific research to the contrary. This perfectibility model leads to the two of the major impediments to a systems approach to reducing medical errors: blaming the individual and punishment as an inducement to improvement (Leape, 1994a). Reason (1997) has termed this approach the "blame cycle."

A second barrier to the establishment of a new cultural approach to medical errors lies in the unique malpractice and regulatory history of the healthcare industry. In contrast to the aviation industry, in which safety investigations are undertaken by regulatory agencies and reporting of incidents is mandatory, the healthcare industry has experienced a climate of fear in the area of malpractice litigation. Concern that a mandatory reporting system recommended by the Institute of Medicine could lead to increased litigation against health care organizations is one of the most frequently cited factors leading to resistance to change in the current system (Pear, 2000). The Institute of Medicine report recommended institutions be compelled to report serious errors that resulted in severe injuries or death of patients, and that the current system in place in twenty states for mandatory reporting be extended to cover the rest of the country (Kohn, Corrigan, & Donaldson, 2000). This mandatory reporting would hold health care organizations accountable for serious errors, fulfill the public's right to know, and provide a strong incentive for health care organizations to improve safety. However, the report also recommends that a voluntary system for reporting safety issues and "near-misses" in which no serious injury occurred be afforded protection from disclosure in a manner similar to the protection currently available for internal Quality Assurance documents (Kohn, Corrigan, &

Donaldson, 2000).

The cultural barriers to adoption of a culture of safety extend into the administrative areas of healthcare organizations as well. Typically, when medical errors are investigated by healthcare facilities, the person committing the error (or end-user of the system, to use a term from systems theory), almost always a physician, nurse, or other clinical caregiver, is normally blamed for the error. The health care organizational leaders, the designers of the system, are virtually never held accountable for the system failures that led to the error. The board of directors of the organization is even less likely to share any of the blame (Donaldson & Gray, 1998). The duty of management and the governing board to quality and patient safety has been seen primarily in terms of physical plant and review of the credentials and competence of caregivers. The changes recommended by the Institute of Medicine in its groundbreaking report would change this dynamic significantly, and both health care administrators and governing bodies would likely find themselves in the position of accountability for the systems, work schedules, and processes that were the root causes of the error (Kohn, Corrigan, & Donaldson, 2000). Finally, addressing root causes may be costly, especially if information technology or facility upgrades are required. In order to confront these root causes in creative ways, a review of the current recommendations in the literature which address error prevention from a systems and human factors approach is thus appropriate.

Strategies for prevention of medication errors

During the past decade, numerous research studies have focused on medication errors, successfully redesigning inpatient ordering and dispensing processes to reduce the incidence of these errors (Bates & Gawande, 2000). Efforts to improve the processes involved in medication administration must also focus on improved detection of latent defects within the system. In

order to accomplish this goal, the culture of fear and reprisal must be changed (Leape, 2000). Leadership based on trust is also cited as critical for the development of a culture where medication error can be reported without fear of punishment (Ryan, 1999). Reporting of "near-misses," for example, offers a free lesson in where the system defenses are weak, and therefore potentially amenable to improvement (Reason, 1997). The use of telephone reporting, particularly for "near-misses," may promote disclosure of errors by decreasing the additional administrative work required for a standard incident report.

Jha (1998) compared spontaneous reporting of adverse drug events (ADEs) with chart review and a computer-based monitor for alerts which indicated that an ADE might be present. A trained reviewer then performed chart audits for detection of ADEs on those records in which the computer had detected an alert. In a review of all admissions at a tertiary care hospital over an 8 month period, voluntary reporting (incident reports) detected only 23 (4%) of all ADEs found. Computer monitoring detected 275 (45%) after analysis of 2620 alerts. Chart review detected 398 (65%) of all ADEs found by at least one method, but was by far the most labor-intensive method of detection (Jha, 1998).

The United States Pharmacopeia (USP), a not-for-profit organization that establishes quality standards for medicines and helps to monitor and prevent medication error problems through national reporting programs, has developed a system called MedMARx, an internet-accessible, anonymous database designed to document, track, and prevent medication errors (USP, 2001). This program allows participating hospitals to benchmark their performance against similar facilities throughout the nation, and provides reports of lessons learned.

Physician computerized order entry (POE), in which the physician uses a computer to order all medications, was shown to reduce inpatient medication errors by 55%, from 10.7 events

per 1000 patient-days to 4.86 events per 1000 (Bates, 1998). Interestingly, the reduction in errors using POE during this study occurred in every phase of the medication process—ordering, transcription, dispensing and administration. As noted earlier, several studies have shown that the greatest likelihood of medication errors occurs during the ordering and administration steps of the process (Bates et al., 1995). Real-world experience with physician order-entry systems has also been positive. The benefits described in interviews with five physicians include orders that are easier to read and track, reduction in errors in the ordering process, more rapid completion of orders, improved patient care with use of order sets and automated reminders, decreased frustration by doctors because the need for finding the patient's chart is eliminated, and order entry from remote sites (HIMSS, 1996). These clinicians, from prestigious academic medical centers such as Johns Hopkins and Vanderbilt, also emphasized the importance of physician involvement in the design of the order entry system, of communication between the systems staff and the clinical caregivers, and of the necessity for the system to be fast and accessible.

A very recent study used a rules-based computer prescribing system accessible from the patient's bedside by portable wireless pen-based terminals (Nightingale, Ada, Richards, & Peters, 2000). This system makes possible warnings about allergies, interactions with or duplications of concurrently prescribed medications, and calculates correct dosages based on the patient's creatinine clearance. It also warns nurses if they attempt to give a drug too soon after its last administration, and suggests the use of alternative drugs when less effective ones are ordered (Nightingale, Ada, Richards, & Peters, 2000). During the 11-month study, the system canceled 58 (0.07%) of orders on grounds of safety, and 427 (57%) of attempted orders which generated high-level warnings were canceled by the prescriber. Transcription errors were eliminated. In a follow-up survey, 82% of doctors and nurses felt that the system was an improvement

(Nightingale, Ada, Richards, & Peters, 2000).

Another exciting development in the area of information technology is the use of handheld computing devices, such as the Palm Pilot, to store drug information. Several free programs, such as ePocrates, are available which allow these devices to synchronize with an Internet website to instantly download the most current drug information and make it available to physicians, nurses, and pharmacists (Epocrates, 2001). The database contains information on adult and pediatric dosing, contraindications, drug interactions, and use during pregnancy, in addition to recommendations for treatment of a number of infectious diseases. As technology advances in this area at an ever-increasing rate, commercial off-the-shelf programs may become available that will allow physicians to perform inpatient order entry from handheld devices.

Leape et al. reported another approach to error reduction, inclusion of a senior pharmacist on physician rounds in an Intensive Care Unit, in 1999. In this before-after comparison, which included a control unit that did not have a pharmacist on rounds, the rate of preventable ordering ADEs decreased by 66%, while the control unit remained unchanged (Leape et al., 1999).

Other techniques of error reduction and mitigation of effects, such as simplification and standardization, as discussed in previous sections, were also evaluated for potential benefits.

Recommendations based on the current literature from organizations such as the Massachusetts Coalition for the Prevention of Medical Errors (MHA, 2000) include use of the unit-dose distribution system for all non-emergency medications, pharmacy based IV admixture systems, and removal of concentrated potassium chloride (KCl) from all nursing units. Especially for handwritten orders, the use of abbreviations is strongly discouraged. In particular, error-prone abbreviations such as "U" for units (which can be easily misinterpreted as a "0", leading to a 10-fold overdose) and "QD" for daily (which can be seen as "QID", four times a

day) and for drug names, which are frequently similar enough to be misinterpreted, should be avoided. They also recommend special procedures for high-risk drugs, using a multi-disciplinary approach. These procedures may include written guidelines, checklists, pre-printed orders, double-checks, special packaging, special labeling, and education (MHA, 2000). Yet another recommendation is that information be made easily available to clinicians about all aspects of drugs through pharmacist rounds with doctors and nurses, pharmacy newsletters, computer aids, and similar methods (MHA, 2000). The basis of this recommendation is the finding that lack of drug knowledge is a frequent cause of errors in the ordering process (Leape et al., 1995). As noted above, pharmacist participation on rounds has been clearly shown to reduce errors. The MHA (2000) further suggests that orientation and periodic education in the medication processes will make clinical staff more aware of both the system and of the resources available to enhance their knowledge of medications. Finally, they recommend a pharmacist on call 24 hours a day to provide expertise if needed.

Long term information technology solutions recommended by the MHA (2000), the American Society of Health-Systems Pharmacists (1996), and many others include physician computer order entry, automated medication administration records (MARs), robots for filling prescriptions, bar coding of medications and patients' wristbands, automated dispensing devices, and computerized adverse drug event detection. These strategies are thoroughly reviewed by Bates (2000), a leading researcher in the field for the past decade.

The Institute for Healthcare Improvement (IHI, 2001) recommends many of the preceding steps, but has suggested a number of other strategies as well. These include periodic review of error data and redesign of processes by multidisciplinary teams, routine analysis and use of error experiences from other organizations to target improvements in the medication process, and rules

pertaining to schedules for all those working in the medication process to prevent fatigue-induced errors. They recommend that prescribers work no more than 24 consecutive hours and that nurses and pharmacists work no more than 12 consecutive hours (IHI, 2001). They also suggest that prescribing errors detected in the pharmacy are recorded, analyzed and used for system redesign.

Since acquisition of the hardware, software, and integration with current systems may make inpatient physician order entry an expensive long term solution, interim alternatives may be useful. One system available for overcoming the problems associated with getting orders to the pharmacy is the PyxisConnect Physician Order Management System (Pyxis, 2001). This system allows the nurse to scan an order sheet into an e-mail-type document, and pharmacy personnel are alerted to the new order. They then open a digital image of the order (better resolution than a fax), and the nurse receives immediate feedback that the order was received. STAT orders can be flagged to allow easy triage. Orders are stored on a CD-ROM, and tracking of order turn-around time is automated.

It should also be noted that numerous research opportunities are now available in the field of error reduction. For example, the National Patient Safety Foundation is providing grants for academic medical centers for projects relating to identification of causes of error and to prevention strategies (NPSF, 2001).

Purpose

The results of an analysis of inpatient medication errors at a military academic medical center, which was based on the causes of medication errors as described by current research in the field, were used as a framework for prioritizing elements of the current system which offer opportunities for significant error reduction. This framework was combined with an examination

of the current inpatient medication processes, a review of recommendations on error reduction from the literature, and an investigation into the currently available information technologies to develop a prioritized plan of action to address the systemic factors which are the root causes of inpatient medication errors at this medical center.

Method and Procedures

The academic medical center chosen for this study is a highly respected tertiary care facility, with a well-deserved reputation for high quality care, an outstanding score on a recent Joint Commission for Accreditation of Healthcare Organization survey, and consistently high patient satisfaction scores on the Department of Defense surveys of all military medical treatment facilities. All incident reports for the calendar year 2000 involving an inpatient medication error from this military medical center were reviewed, with an emphasis on identifying system factors which set the stage for the error. To the extent data on the incident report form allowed, each incident was analyzed in regard to the end-user of the system who committed the error, location of unit where the error occurred, type of error, the medication and medication class involved, time of day the error occurred, stage of the medication process where the error occurred, whether the error was caught before reaching the patient, actions taken to prevent future similar errors, and degree of patient harm as a result of the error. System factors which represent latent errors in the process were categorized as 1) related to the medication itself (e.g. sound-alike/look-alike drugs, high-risk medications), 2) problems in the ordering process (e.g. legibility, transcription errors, faxed orders, verbal orders), 3) management factors (e.g. information systems, work schedules, environmental factors, distractions, high patient acuity to staff ratios), and 4) patient factors (e.g. similar names). The data was entered into the SPSS software package. Each variable was analyzed in a one-way frequency distribution to determine

the relative contribution of that factor to the total number of errors. Effects of workload on the relative frequency of reported numbers of error were estimated by adjusting error rates by occupied bed days for each unit, as the data systems used were unable to provide the total number of medications administered on each nursing unit. Tables, Pareto graphs and, when appropriate, pie charts were used for presentation of the relative contributions of each system factor. The total number (n) of inpatient medication errors analyzed was 155 errors for the year 2000.

Next, an analysis of the current inpatient medication process was accomplished by personal observation and interviews with pharmacists, nurses, physicians, and technicians. Flow charts of the current processes were developed for medication processes; these were subdivided into (1) physician order process, (2) nursing order process, (3) nursing medication administration process, (4) nursing documentation and assessment process, and (5) pharmacy processes. Differences in processes depending on whether the medication was stocked on the unit or obtained from the pharmacy were included. These flow charts were validated by multiple nurses and by a pharmacist. The benchmark error reporting and reduction system at the Veterans' Administration was evaluated for potential best practices by direct observation and interviews with pharmacists and nurses. Barriers to implementation of error reduction strategies in this medical center were also assessed through interviews and observation.

The results of the statistical analysis were then reexamined in terms of the flow charts to determine where latent system defects, as shown in the incident report analysis, may be opportunities for improvement. Available technology, such as inpatient physician order entry (POE) and automated medication administration records (MAR) was assessed for likelihood of impact on improvement in the medication processes. Other techniques of error reduction and

mitigation of effects were also evaluated for potential benefits, as were recommendations based on the current literature from organizations such as the Massachusetts Coalition for the Prevention of Medical Errors (MHA, 2000) and the Institute for Healthcare Improvement (IHI, 2000).

Finally, a prioritized list of recommendations for an action plan was developed, along with supporting evidence from the literature, documentation of the results of the incident report analysis, and an estimate of costs for any recommended technology or equipment purchases. Actions which were judged to have potential for reducing errors were classified as "already completed or initiated", "short-term", and "long-term" actions, and were entered into a matrix, along with the problem which each solution addressed and estimated costs for technology, if available. Costs for additional technology or recommended equipment were estimated based on projects by similar organizations, or from publicly available information, when possible. A separate section, entitled "Additional Activities", made recommendations for actions not related to the incident report or medication process analyses, but which the institution might want to consider. These recommendations were forwarded to the Pharmacy and Therapeutics Committee through the hospital Risk Manager, Chief Nurse Executive, and the Chief of the Medical Staff.

Because this study relied on data protected from disclosure by Title 10 of the United States Code, Section 1102, it was necessary to delete any references to the specific institution studied and to use the generic term "military medical center". The final report was submitted to the medical center's Risk Manager and the medical law consultant for permission for release in accordance with applicable service instructions.

Results

Results of Medication Error Data

155 total inpatient medication errors were reported through the incident report process for CY 2000. Based on 16,902 admissions and 54,625 occupied bed days for 2000, this translates into an error rate of .92% errors per admission, and a rate of 2.8 errors per 1000 occupied bed days. One unit, 7A, reported 43 errors, which was 27.7% of all errors reported from the 14 inpatient nursing units in this institution (Table 1). These results are also shown in Pareto chart format at Figure 1 in Appendix B.

The raw number of reports was then adjusted by each unit's occupied bed days for 2000, as accurate data on differences in the number of medications administered on each unit was not available. Data from the intensive care units were not included in the adjustment because these sicker patients were less likely to be comparable to those on the other nursing units, as intensive care unit patients are more likely to receive a larger number of medications per day than non-ICU patients. With these adjustments, two nursing units, 7A and 6D, were found to have the highest rates of reporting; these two units accounted for 60 (38.7%) of all errors reported (Table 2). By contrast, the two units with the lowest percentage of reporting, 9D and 1A, had rates of reported incidents less than one-seventh the rate of the two highest units (43.7% vs. 6.7%). Using a goodness-of-fit test, comparing actual error reports per 10,000 occupied bed days with expected values if all units reported equally, a statistically significant difference was found, with $p < .001$. (Appendix B, Figure 2).

Table 1.

Medication Errors Reported by Unit

Unit	Number of errors	Percentage of total errors
7A	43	27.7
6D	17	11.0
SICU	15	9.7
PICU	14	9.0
8A	14	9.0
NICU	10	6.5
2B	10	6.5
3C	9	5.8
9D	8	5.2
MICU	6	3.9
CCU	5	3.2
1A	2	1.3
3A	1	.6
ED	1	.6
TOTAL	155	100.0

The types of drugs involved in reported errors are shown in Table 3 and in graphical format in Figure 3, Appendix B. Antibiotics, narcotics, and IV solutions accounted for 77 errors (49.7% of the total number of errors). Although the miscellaneous category was the largest, it was comprised of small numbers of errors in a wide variety of medications. These include

antihypertensives, insulin, electrolyte solutions, and a variety of gastrointestinal drugs. A full listing of all drugs included in the miscellaneous category is found at Appendix C.

Table 2.

Medication Errors by non-ICU Units, Adjusted for Occupied Bed Days for CY 2000

Unit	Number of Reported Errors	Occupied Bed Days CY 2000	Errors per 10,000 Occupied Bed Days
6D	17	2807	60.6
7A	43	10916	39.4
8A	14	4925	28.4
2B	10	6834	14.6
3C	10	6959	14.4
1A	2	2638	7.6
9D	8	12630	6.3

Of the antibiotics, the largest single class of drugs involved in reported medication errors, the drugs with the highest numbers of errors were vancomycin (11), gentamycin (9), Zosyn (5) and Ancef (4). A recent change in the manufacturer's administration recommendations for vancomycin was felt to account, at least partially, for the high number of errors for this drug.

The types of errors reported are shown in Pareto format at Figure 4, (Appendix B) and at Table 4. Three types of errors, missed dose(s), late doses, and wrong dose(s), accounted for 51% of all errors reported. An incorrect medication administered to the patient occurred in 18 (11.6%) of the errors, and the patient received unordered additional doses of a correct medication in 16 cases (10.3%). Only 11 reports (7.1%) reflected an error which did not reach the patient.

Table 3.

Class of Medication involved in Reported Errors

Medication class	Number of errors	Percentage of total errors
Antibiotic	46	29.7
Narcotic	16	10.3
IV solution	15	9.7
Steroid	7	4.5
Anticoagulant	7	4.5
Antifungal	6	3.9
Chemotherapeutic agent	6	3.9
ACE inhibitor	3	1.9
Non-steroidal anti-inflammatory drug	2	1.3
Miscellaneous	47	30.3
Total	155	100.0

The processes in which the reported errors occurred are shown in Table 5 and in Appendix B, Figure 5. Errors noted in the ordering process occurred in 100 (64.5%) of the incidents reported. These errors most commonly occurred in the transcription process and in the use of the fax machine to communicate orders to the pharmacy. Problems related to the ways in which physicians order (such as handwriting, verbal and telephone orders, and delays in the order being noted by the nurse) accounted for 32 (37.6%) of errors in the ordering process. The transcription process was involved in 31 (36.5%) of the errors involving the ordering process, and problems with faxes accounted for an additional 15 (17.65%). Dispensing and administration errors were

less commonly reported.

Table 4.

Types of Reported Medication Errors

Type of error	Number of errors	Percentage of total errors
Missed dose(s)	33	21.3
Late dose	27	17.4
Wrong dose of correct drug	19	12.3
Wrong medication given	18	11.6
Extra dose(s)	16	10.3
No error reached patient	11	7.1
Infusion too rapid	8	5.2
Dose given too early	6	3.9
Infusion too slow	5	3.2
Medication not stopped when ordered	3	1.9
Wrong patient received drug	3	1.9
Duplication	2	1.3
Given IV instead of IM	2	1.3
Incorrect PCA parameters	1	.6
Precipitation in IV line	1	.6
Total	155	100.0

Table 5

Processes in which Reported Errors Occurred

Process	Number of errors	Percentage of errors
Ordering	100	64.5
Administration	42	27.1
Dispensing	13	8.4
Total	155	100.0

Management factors, including information systems, were found to be factors in 104 (67.1%) of all errors reported. The most common system cause was related to information systems, which were a factor in 49 (31.6 %) of all errors reported. Other system causes were lack of communication/teamwork and distractions (Table 6, and Figure 6, Appendix B).

Errors related to the medication itself (look alike or sound alike drugs) were infrequently reported through these incident reports. In only 21(13.5%) of the reports were these factors mentioned (Table 7). Causes related to patient factors, such as similar names, were even less frequently mentioned, accounting for only 4 (2.6 %) of all errors reported.

Table 6.

Management Factors in Reported Errors

Management Factor	Number of Errors	Percentage of Errors
Information systems	49	35.8
Unknown	33	24.1
Teamwork/communication breakdown	23	16.8
Distractions	9	6.6
New staff	8	5.8
Other	15	10.9
Total	104	100.0

Table 7.

Medication Factors in Reported Errors

Medication Factor	Number of Errors	Percentage of Errors
Unusual standard dose time	9	5.8
Names look alike	5	3.2
Similar packaging	3	1.9
Medications look alike	3	1.9
Infusion solution requirements	1	.6
Not listed as a factor	134	86.5
Total	155	100.0

The distribution of errors which were reported occurred throughout the day (Table 8).

These differences were not statistically significant ($p > .05$). A pie chart of this distribution is shown at Appendix B, Figure 7. Nurses were by far the most common "end-user" of the system, accounting for 125 (80.6%) of the reported errors (Figure 8, Appendix B). In five errors, a physician was the end-user, and in one case a CRNA was noted to be the end-user of the system. While physician errors were infrequently reported, interns and residents were involved in four of the five incidents reported. Two of these incidents involved large overdoses (8 and 10 times the recommended dose) of medications, presumably due to a lack of adequate knowledge of correct doses.

Table 8.

Times of Reported Medication Errors

Time	Number of reported errors	Percentage of errors
0001-0400	14	9.0
0401-0800	19	12.3
0801-1200	31	20.0
1201-1600	21	13.5
1601-2000	22	14.2
2001-2400	19	12.3
Unknown	17	11.0
Multiple times	12	7.7
Total	155	100.0

Reporting of inpatient medication errors at this institution appears to be performed primarily by the nursing staff. In addition, counseling of nursing personnel and briefing nursing

staff are by far the most common actions taken as a result of medication errors reported through the incident report process (Figures 9 and 10, Appendix B). Although some reports attempted to address systems factors, such as chartering a Performance Improvement team, the incident reports themselves do not necessarily reflect the hospital's efforts to improve the medication processes involved.

The incident reports were found to be an adequate source of information about the extent of patient injury in only 63.2% of the reports. Table 9 shows the extent of patient harm as determined from the incident reports. In 59 (38.1%) of all incident reports, no injury to the patient was reported, or it was determined that no injury could be expected due to the type of error. In 12 (7.7%) reports the error was intercepted prior to reaching the patient. In only one case was the error reported to have contributed to a patient's death.

Table 9.

Patient Harm as Determined From Incident Reports

Patient Harm	Number of reports	Percentage
No injury	59	38.1
Unable to determine	57	36.8
Minor injury	22	14.2
Near miss, intercepted before reaching patient	12	7.7
Moderate injury	4	2.6
Contributed to death of patient	1	.6
Total	155	100.0

The reliability of the incident report data was judged to be good, as the reports were not a

sample, but included every report generated for an entire calendar year, with $n=155$. A one-year period was chosen for the review because changes in processes, such as the use of fax machines, may make earlier data representative of past processes, not the ones currently in use. Some information was incomplete, most notably that on patient outcome, as discussed above, but other data, such as the type of error, drug involved, and time of day, were consistently reported. Face validity was achieved by analyzing only information present in the incident reports themselves. The researcher is also a physician with 25 years experience in inpatient settings, and received frequent assistance from both nurses and pharmacists in interpretation of the incident reports.

The extent of under-reporting of errors, however, could not be determined from this study. The literature suggests that only a fraction (4-6%) of actual errors in hospitals are reported through the incident report mechanism (Cullen, 1995). The types of errors found at this facility are consistent with those discussed in the literature as well as with the errors which could be predicted based on the analysis of the medication processes involved. Finally, nurses, pharmacists, and physicians indicated during interviews that they believed the results were a valid representation of the types of medication errors that occur in the organization.

Results of Analysis of Current Medication Processes

Results of the development of flowcharts for the inpatient medication processes are shown in Figures 1 through 6 (Appendix D). As can be seen from the flowcharts, these processes are extraordinarily complex, involving physician staff, nurses, ward clerks, admissions personnel, pharmacy personnel, and the information systems of the entire organization. The flowcharts were based upon processes described by physicians, nurses, and pharmacy personnel, and were validated by nurses throughout the facility and by the chief of the inpatient pharmacy.

Although physician order entry is possible with the Composite Health Care System

(CHCS), the Department of Defense patient computer system used at all military hospitals, the process is not user-friendly, the interface is text-based, and the system is quite slow. The ordering of IV drugs is particularly problematic in this system, as it requires the person ordering to know in what solution a drug should be diluted in order to place an order for that medication. Neither nurses nor physicians have this knowledge, and CHCS does not provide it.

Consequently, except in the case of pre-printed orders, orders in this facility are handwritten, and poor handwriting, inappropriate use of abbreviations, and confusing orders can occur. Samples of the problems which did occur with handwritten orders, as noted through the incident report process, are shown in Appendix E. The use of abbreviations was noted frequently.

The complexity and lack of shared information on the status of orders sent to the pharmacy results in frustration for both nursing and pharmacy staff. Nursing personnel make numerous phone calls to try to find out the status of a particular order when it is not received. Pharmacy personnel are thus distracted from their work by the phone calls. Since there is no tracking mechanism, are often unable to give the information the nurse is requesting. A Mostler[®] transit tube system was present in the hospital for distribution of pharmacy orders, among other things. In addition to problems created by faxed orders, if the order is sent through the transit tube it may be accidentally picked up by a nurse from a different unit, due to the placement of the tube outlets in locations other than nursing stations. The fax machines and the tube system thus create "black holes" where no one knows what the status of a particular order is at any given time after it is sent into the system. Lack of continuity with changes of shift exacerbates these problems, as do changes in the patient's location. If the patient location is incorrect in CHCS, pharmacy may send a medication order to the wrong unit. The current admissions process requires

administrative personnel, who are located in a separate office far from the patient units, to enter changes of room or unit into CHCS; the nurses cannot make these changes. Even if policy allowed nurses to enter the changes, it is doubtful that the process would be significantly improved because of staff resistance to use of CHCS. Several nurses and pharmacists who had had experience with improved systems in other hospitals indicated that they felt the systems in use at this facility were so antiquated that they were in danger of losing skills necessary for future employment opportunities. Many others indicated an interest in developing the computer skills that they felt would become increasingly expected of all healthcare professionals in the future.

The current system also fails to make drug information and decision support available to clinical staff at the point of care. Although the organization provides access to Micromedex, a drug information resource providing information on dosage, pharmacokinetics, cautions, interactions, clinical applications, and comparative drug efficacy (Micromedex, 2001) through its intranet, many nurses indicated that they were unaware that this resource existed, and instead relied on textbooks for drug information. Limited availability of intranet-accessible computers on the nursing units may contribute to the failure to use an available resource; the only computers available in most medication rooms have access only to the CHCS system. With the large number of physicians in training programs, demand for computers on the nursing units frequently exceeds the supply. Some physicians were also unaware of the Micromedex resource.

Orientation to the medication process for newly assigned staff is also suboptimal. Nurses in a nurse internship program receive an orientation to the pharmacy, during which the inpatient medication process is presented. Nurses reassigned from other hospitals, however, do not receive either an orientation to pharmacy or to the CHCS system. New physicians generally receive at

least a brief CHCS orientation, but this is provided by information systems personnel. Neither newly assigned nurses nor physicians transferred from other hospitals receive a formal orientation to pharmacy or to the medication process.

Yet another factor impacting the current medication processes is a result of facility design. This hospital has been converted over the past ten years from an inpatient facility with nearly 1000 beds to an organization with approximately 300 inpatient beds. Increased outpatient and administrative functions have displaced former inpatient units, with the result that there are isolated nursing units on eight different floors of the building, interspersed with offices, clinics, and various support functions. The surgical suite and the oncology unit have separate pharmacies which fill their orders during normal duty hours, but the other units are supplied by an inpatient pharmacy located in the basement. The resultant logistical problems add to the complexity of the system. For example, nurses caring for ICU patients must leave these critically ill patients to go to the inpatient pharmacy to sign out narcotics during the night.

The medical center has taken steps to improve its approach to patient safety and error reduction, and several pilot programs have begun. A critical care pharmacist was assigned to the ICUs in 1999; he makes rounds with clinical staff in these units, provides expertise in all facets of medication use, and has documented an average of 5.11 interventions per day in the medication ordering process (Dunlop, D., personal communication). The hospital is participating in a collaborative entitled "Improving Safety in High Hazard Areas" sponsored by the Institute for Healthcare Improvement (IHI) and the Quality Interagency Coordination Task Force (QuIC). The long-range goal of the collaborative is to improve safety in high hazard areas (such as the ICU and Emergency Department) in the participating hospitals, and to begin to communicate achievements to other hospitals in the military and the VA systems throughout the country (IHI,

2001). The Department of Defense has funded a central contract for a number of military hospitals with the United States Pharmacopeia (USP) for a test program of the MedMARx national reporting and database system. However, this medical center was not selected to participate. The facility has expressed interest in pursuing this option with its own resources.

The VA Medication System

A discussion of a current state-of-the-art in medication error prevention program can provide insight into best practices and offer a road map for what a system focused on patient safety looks like. The Audie L. Murphy Veterans Hospital in San Antonio, Texas, like many VA hospitals throughout the U.S., has moved aggressively to design systems which make "doing the right thing right" easy, and making errors much more difficult. The entire hospital focuses on a system approach to error, and error reporting is not punished. The incident reporting form used is short, with many check-off boxes to decrease requirements for the narrative portion of the report (Appendix F). Patient outcomes and additional resource utilization as a result of the error are easy to complete, and systems factors are listed to remind personnel to think beyond the immediate "cause" of the error. Near-misses and errors are reported to a central Patient Safety office for the entire VA system, where an interdisciplinary expert team reviews each serious error. This team provides feedback to the hospital reporting the event, as well as disseminating lessons learned to the entire VA system (Leape, Woods, Hatlie, Kizer, Schroeder, & Lundberg, 1998). A senior pharmacist is assigned full time to improving the quality of medication processes throughout the hospital. She reviews a discharge summary on every patient, looking for clues to potential adverse drug reactions or for possible errors. Medical records are reviewed if potential problems are found, and the errors found are reported to the Pharmacy and Therapeutics Committee for redesign of systems if needed. A senior nurse, with a strong clinical background

and systems orientation, is assigned full-time to act as a liaison between the nursing departments and the systems personnel, and she provides extensive education to the nurses throughout the facility. She also spends considerable time coaching on the wards. Informational packets containing a hospital formulary, IV incompatibility information, standardized medication times, and food-drug interactions are also given to each new nurse during a pharmacy orientation.

Physician order entry is the standard throughout the facility. Physicians are alerted if a drug allergy or incompatibility is present. All medications and all patient wristbands are bar-coded. The nurses use a small computer, equipped with a bar-code reader, on top of the medication cart to check each medication and each patient prior to administering every drug or hanging an IV. Audible and visual alerts warn the nurse when the software detects any problem in the process, such as a wrong dose or wrong patient. This ensures that the right patient gets the right drug at the right time, and the exact time of administration is automatically entered into an automated MAR. The system will run "due lists", alerting the nurse about all the medications due in a specific time period. It also reminds the nurse to check for effectiveness of "as needed" medications. If a drug which is scheduled to be administered to a patient is not present, a missing dose request form prints out automatically in the pharmacy, and the system captures all relevant data to determine the cause of the missing dose for management review. A patient medication log, showing the number of times a drug has been given for any specified time period is accessible to clinicians anywhere in the facility. In addition, nurses may record vital signs pertinent to the drug being administered. The system is flexible enough to allow one-time, STAT, and on-call orders to be entered, as well as regularly scheduled medications. A final benefit of the medication administration software is that it generates extremely accurate data on drug utilization (and associated costs) for each patient, physician, unit, and service.

Much of the pharmacy dispensing workload has been transferred to a robotic system, allowing the pharmacists to actively participate in patient care on the units. Each patient has both an admission and discharge note written by the pharmacist assigned, and pharmacy personnel regularly inspect wards to remove outdated or deteriorated ward stock. Bags of IV piggyback medications are prepared in large batches to assure good manufacturing practices and uniformity. Standardized preprinted forms, labels, instructions, and directions are used for chemotherapeutic drugs and research medications. Numerous publications about error prevention have raised the level of awareness of staff about medication errors.

Of note is that the original VA computer system, the Decentralized Hospital Computer Program (DHCP) was the model for the military's CHCS computer system. In 1996, the VA introduced the Veterans Health Information Systems and Technology Architecture (VISTA), which is built on an open system, client-server architecture, which ties together workstations and personal computers with a graphical user interface. DHCP is now only a part of VISTA, which includes links that allow commercial off-the-shelf software and products to be used with existing and future technologies (VA, 2001). The current VISTA system was critical to the deployment of the medication administration software.

Discussion

Medication Error Data

Analysis of the incident report data for CY 2000 shows that this medical center is quite similar to hospitals whose results are reported in the literature. Ordering errors were found in a study of inpatient medication errors at two Boston teaching hospitals to account for 39% of adverse drug events, and transcription errors 12%, for a total of 51% (Leape et al., 1995). These results are similar to those in this study, where the combined order/transcription processes

accounted for 64.5% of the errors. In the current study, due to use of the incident reports as the data source, it was not possible to clearly separate ordering errors from transcription errors. The Boston study also found that errors in the ordering process, as a result of a lack of knowledge of the drug, occurred in 35% of the preventable ADEs, and were most frequently caused by physicians (Leape et al., 1995). In interviews with nurses and pharmacists, it was apparent that errors in physician orders that are corrected by the nurses or pharmacists are not usually reported through the incident report system at this medical center.

The marked variability in reporting from the various nursing units, and the overall infrequency of reported errors, is also of note. Estimates of the error rate in similar institutions, based on incident reporting, vary from 4-6% of all admissions, and 10.7 errors per 1000 patient days (Bates et al., 1995; Lazarou, Pomeranz, & Corey, 1998). This facility's rates of .92% errors per admission, and 2.8 errors per 1000 patient day, are thus quite low. In particular, ordering errors by physicians appear to be significantly underreported compared to that expected from the literature.

National studies show only about 4-6% of all true errors get reported through the incident reporting mechanism (Cullen, 1995; Jha, 1998). Of the incident reports in 2000 at this medical center, only 7.7% of the reported errors were near-misses. The general understanding of most personnel is that near-misses are not reportable, as no true "incident" for which the hospital may be held liable has occurred. In 59 (38.1%) there was no injury, and in an additional 57 (36.8%) information was insufficient to determine the extent of injury. This underreporting may be a result of the lengthy narrative required on the current form, fear of punishment for reporting, a lack of awareness of the importance of reporting in order to effect system changes, or simply forgetfulness due to heavy patient workloads.

In the overwhelming majority of reports, a nurse is the end-user of the system, and individual blame is the norm. This blame falls predominantly on the single nurse whose "fault" the error was; the nurse is "counseled" and system factors are rarely addressed. Not surprisingly, this approach, called the "person" approach by Reason (2000), leads to a recurrence of similar errors, by a variety of end-users, throughout the institution. The practice of assigning blame to individuals may also contribute to decreased reporting, particularly if there is no harm done to the patient. Although most nurses reported that they did not fear the consequences of reporting errors, many admitted that it was easy to "forget" to do it if they were busy. In some instances, however, the incident reports do reflect a root cause analysis, and a system problem was addressed.

Current Medication Process

Analysis of the current medication processes reveals a system similar to that in use in most hospitals in the U.S. today. This system is notable for its complexity, its lack of standardization, its reliance on memory, and its inability to consistently detect errors before they reach the patient. For example, the current medication process contains a minimum of 22 separate steps in which an error can occur. If each step in the process were always performed correctly 99% of the time, the rate that a medication was given correctly would be, at best, 80% $[(.99)^{22} = 0.802.]$ However, many steps in the process are error-prone, because they either require reliance on memory or involve a time-consuming attempt to find a patient's record or to look up information in a reference book. Reliance on memory has been clearly shown to increase the rates of errors in complex systems. The extremely high informational requirements of safe medication prescribing and administration only add to the increased likelihood of error. Because reference books may become outdated quickly, due to the large number of new medications approved for

use each year, this step may be unproductive as well. The newer medications, the least likely to be found in a reference book, are the ones with which a nurse or physician may be most unfamiliar.

In addition, the current process is notable for its traditional approach and structure. With the exception of the use of a fax machine to send orders to the pharmacy, and CHCS to check allergies and drug compatibilities in the pharmacy, this process is essentially the same one used in most hospitals in the 1970s. As previously noted, these traditional medication processes were never designed; they evolved over many years, long before the advent of computers, and in a time when informational requirements were far less than those of 21st century medicine. The medical profession has been slower than other industries to adopt automation for other than administrative purposes. For example, although physician order entry is possible with the current information systems present in the organization, the process is not user-friendly, the interface is text-based, and the system is slow. The result has been that the inpatient order entry system has been shunned by both nursing and medical staff. Lack of physician order entry produces duplication of effort at every stage of the ordering process, leads to numerous transcription errors, and results in an increased risk of liability for the organization due to poor handwriting. Additionally, a computer-generated MAR is available, but it is also not used by the nursing staff, and most nurses are unaware that it can be generated from CHCS.

The lack of computer training and orientation to the medication processes in the facility contributes to unmet expectations and therefore a lack of teamwork, particularly between the pharmacy and nursing services. In addition, many nurses reported dissatisfaction with the process because they had previously worked in civilian hospitals where the medication processes were computerized.

The complex interaction required by administrative personnel, IM/IT staff, nursing personnel, medical staff, and pharmacy personnel in order to make the current medication processes effective have been noted earlier. However, the organizational structure at this medical center results in administrative separation of the pharmacy, information systems and admissions departments from the clinical (medical and nursing) staffs. The first position in the hierarchy with authority over all four areas occurs at the level of the hospital CEO. A lack of teamwork is also reflected in the tendency of nurses and pharmacy personnel to blame each other when errors occur, particularly for delays in obtaining needed medications.

A number of structural elements, including the transit tube system and the overall design of the aging facility were also noted to have an impact on the delivery of medications to the nursing units. These issues are being addressed, as appropriated funding allows, with modernization of the facility. The contribution of these factors was determined to be minor compared to the costs of replacement.

Limitations of study

Only incident reports were available for this study and as noted previously, significant under-reporting may be present. Other sources of medication error data, such as investigations of injuries felt to represent potentially compensable events (potential malpractice claims) were not available. Additionally, information about physician ordering errors corrected by pharmacy or nursing personnel were not collected or tracked, and could not be included. Because incident reports do not contain patient names, and due to the structure of the reports themselves, it was not always possible to determine whether an error had caused any harm to a patient, or whether additional monitoring or increased intensity of services were required due to the error. Very few reports were received from areas where surgical or other invasive procedures were

accomplished; as these areas represent especially high-risk areas for medication errors involving parenteral drugs, which would be more likely to result in significant harm to patients, the lack of reporting is troublesome.

Barriers to Implementation

Perhaps the most important barrier to any change in a long-established system such as the medication administration process is organizational inertia. A consensus must be built, first in the organizational leadership and then in the entire staff, that the process needs to be changed, and that the anticipated results of change are worth the commitment of resources and energy required. A second cultural factor, the attribution of blame to individuals for errors - the "perfectibility model" - must also be overcome throughout the organization in order to effect change to a systems-oriented approach. As shown by the high proportion of nurses and technicians receiving counseling for errors reported through the incident report process, this medical center, like many throughout the nation, continues to blame the end-user of the system when latent defects lead to errors.

An interrelated factor is the current structure of medical center. The clinical functions tend to follow entirely separate chains of command from support functions until the level of the CEO is reached. This bureaucratic design appears to impede effective communication, lead to even more blaming behavior, and detract from teamwork and problem solving. These effects require considerable effort and are only partially overcome by dedicated personnel at the unit level. The work of multidisciplinary committees, such as the Pharmacy and Therapeutics Committee, may also be more challenging.

The major Information Management/Information Technology (IM/IT) barrier to implementation of a truly outstanding medication process, such as that found at the VA Medical

Center, appears to be the Department of Defense (DoD) computer system CHCS. This proprietary system, procured in the late 1980s from Science Applications International Corporation (SAIC), uses the programming language MUMPS, which was developed in the 1970s (SAIC, 2001). Because CHCS is proprietary, the numerous upgrades required since its original procurement have been costly, and the system has been unable to keep pace with the rapid development of newer technology. Commercial off-the-shelf products cannot be used with CHCS. The proprietary nature of the system results in the necessity for very expensive contracts in order to develop CHCS-compatible applications.

Future upgrades planned by the Department of Defense, including CHCS II, are projected to bring the system into compliance with HL7 standards, and to allow a fully computerized patient record (CHCS II, 2000). However, according to B. Dawkins (personal communication, 28 Dec 2000), Project Manager for CHCS II, this system has been delayed, and is currently not projected for deployment until mid-2002. The CHCS II Office is also evaluating COTS products to provide a more robust inpatient order entry system which will interface with CHCS II. The medical center investigated the possibility of procurement of a system, CIS (Clinical Information System), but this system, which is in use at several other military hospitals, is unable to download information into CHCS. It thus solves only the legibility problem but not the duplication of effort or potential transcription errors, as pharmacy personnel are required to re-type the drug orders into CHCS.

Conclusion

Although the medical center chosen for this study is an excellent facility, with high scores in objective measures of both quality and patient satisfaction, it has opportunities for improvement in its medication systems similar to the ones found in other studies of medication

errors. Like other medical centers and hospitals described in the literature, the medication processes at this facility were never consciously designed. They evolved over many years, and are similar to the majority of other hospitals throughout the US. However, the scientific evidence is now clear that the traditional medication processes, incident reporting mechanisms, and assignment of blame to individuals are ineffective in reporting medication errors and in preventing harm to patients. What is also clear from the literature is that system redesign can improve patient safety and enhance the quality of the care delivered by these institutions.

The current study clearly shows that the steps in the medication process which appear to offer the best cost-benefit ratio are those related to information management and information technology, particularly as they apply to the ordering and administration processes. Of the 85 errors (55% of the total number of errors) in which the ordering process was a factor, fully 53% (45 errors) involved poor IM/IT as a factor. In the 104 errors (67% of the total number of errors) in which management factors were involved in an error, information systems were involved in 49 errors (47%). The study also offers evidence that errors are under-reported at this hospital, with reported error rates far below those found in similar institutions described in the literature. The frequency of counseling as the action taken in response to errors also indicates that a cultural shift toward a systems approach rather than one focused on the individual would benefit the organization.

Because the best long-term solution, an inpatient order entry, decision support, and bar-coding system similar to that in use at the VA, must await funding and development at the level of the Department of Defense, interim shorter-term solutions are necessary. Emphasis in development of the prioritized list of recommendations was on changing the culture of the facility and on improving reporting of errors, as these are the critical first steps toward redesign

of the entire system. Secondly, error prevention strategies in the ordering process, transcription, and communication between the pharmacy and the nursing staff were addressed, primarily through improved IM/IT.

Recommendations

A matrix of recommendations for this facility is found in Appendix G. The systems factors and processes which led to the most frequent errors provide a framework for prioritizing error prevention strategies. This study can be used to strengthen resource allocation decisions (personnel, equipment, space, and funding) when improvements in the system factors affecting medication errors are considered.

The matrix of recommendations shows the actions as (1) already completed or initiated, (2) short term, (3) long term, and (4) additional actions. However, these recommendations can also be categorized by the common problem addressed: improved reporting, cultural change, ordering and transcription, dispensing, administration, and documentation. Each problem and the various actions to address that problem will be discussed separately.

Cultural Change

A change in organizational culture away from the person-based "blame cycle" mindset to a systems approach is a prerequisite for effectively addressing the entire issue of medical errors in general and medication errors in particular. A belief in the perfectibility model must be replaced by the realization that all humans err, and the design of systems to make it easy for dedicated caregivers to do things right must be a priority of senior management. In addition, the acceptance of the status quo must be replaced by a passionate commitment, similar to that of NASA, to the identification and redesign of the underlying defective systems processes which cause errors to occur throughout the organization.

Improved reporting

The medical center has developed a telephone system for anonymous reporting of near-misses, which should be widely publicized and encouraged. In addition, the incident report system can be made less time-consuming for staff by development of a check-off form, such as that used by the VA, which would decrease the narrative requirements of the form currently in use. This would also allow better tracking of patient outcomes and resource utilization as a result of errors. The hospital should consider becoming a participant in the MedMARx database project in order to benchmark its performance and utilize lessons learned from other hospitals. The cost to participate in MedMARx is approximately \$4090 per year. Pharmacist review of discharge summaries for ADEs, pending acquisition of an information system with monitoring capability for ADEs and errors, is also recommended in order to more accurately determine the extent of medication errors at the facility. This pharmacist could also be designated as the full-time Quality Improvement pharmacist; this would involve assignment of a full-time pharmacist to accomplish these tasks, but would provide significant benefit to the entire organization.

Ordering and Transcription

The ordering and transcription processes accounted for 65% of all errors reported for the year 2000. Therefore, the highest priority has been assigned to both short- and long-term recommendations to address these areas. In the long term, a computerized physician order entry system with decision support is the solution most strongly supported by the literature. However, with the previously discussed problems with the CHCS system, the cost for procurement of a bi-directional, CHCS-compatible, order entry system for a single hospital would be prohibitive. Although the current system allows order entry, it is not viable option for physicians and nurses to use, as it requires detailed knowledge of IV drug preparation only possessed by pharmacists.

Thus, computerized physician order entry must await funding and procurement at the Department of Defense level. Incorporation of national guidelines into the order entry system is an action that is dependent on acquisition of the system, and so is also a long-term solution. Another long-term acquisition is a robotic system to fill prescriptions; based on costs for similar organizations, this could be expected to cost approximately \$1.1 million, and so must be funded through higher headquarters. The robotic system would free pharmacists to participate more fully in direct patient care on the inpatient units, as well as decrease dispensing errors. Finally, flattening of the hierarchical structure of the medical center will require approval by higher headquarters as well, but could lead to the improved communication and teamwork needed for all stages of the medication process, but especially those in the ordering process.

However, several shorter term actions, again based on the literature, could be expected to improve the ordering and transcription processes while awaiting the implementation of computerized physician order entry. These include the deployment of the PyxisConnect system, at a cost of approximately \$4000 per month to lease. Developing standardized procedures for medication processes throughout the hospital, but especially for high-risk drugs, has also been shown to reduce the opportunity for ordering errors. The VA would likely share any protocols it has developed at no cost. Formal orientation to the medication process through pharmacy in addition to CHCS training for all newly assigned nurses, physician staff, and residents could improve communication as well as reduce errors throughout the process. Procurement of handheld devices and use of internet technology, such as the ePocrates database system, would improve knowledge of medications and be far more efficient than the use of reference books, particularly for more recently approved drugs. These devices cost approximately \$200-250 each; putting 5 devices on each inpatient unit would cost less than \$17,000. Finally, improved training

for all nurses in basic computer skills should be accomplished, as this will allow them to use the resources available for drug information, and prepare them to use more sophisticated systems as they become available.

Dispensing

Dispensing errors were found in only 8% of the reported errors in this study. Somewhat surprisingly, computerized physician order entry has been shown to reduce dispensing errors as well as errors in all other stages of the medication process. Until such a system can be obtained, short-term strategies for error reduction should include expansion of the unit dose distribution system to include all non-emergency medications and continued use of the pharmacy IV admixture process. Many of the strategies discussed in the ordering section have also been shown to reduce errors in the dispensing process. Because of the relative infrequency of errors in dispensing, however, no additional high-cost equipment is recommended solely to address errors in this process.

Administration and Documentation

Administration and documentation errors comprised 27% of the errors reported. As previously discussed, the acquisition of a computerized physician order entry system has been shown to reduce errors in the administration of medications. The addition of a bar-coding and scanning system would enhance the capability of this system to reduce errors in both administration and documentation. The bar-coding system for the VA cost \$650,000, and costs for this hospital of similar size could be expected to be comparable, once CHCS II allows commercial off-the-shelf systems to be integrated. Availability of pharmacists on the inpatient units would make their expertise available to nursing staff, which could reduce administration errors, but this remains a long term action due to the pharmacy manpower required. Similarly,

redesign of the facility to improve the current logistical problems in getting medications to the inpatient units must await funding for facility upgrades.

In the shorter term, special procedures for high risk drugs have the potential to reduce administration errors, as do many of the steps already discussed to reduce ordering and transcription errors. Lastly, allowing the surgery pharmacy to dispense controlled drugs to the ICU nurses could prevent delays in these critically ill patient receiving their medications and enhance the efficiency of the ICU nurses.

Research

As an academic medical center, this organization has the opportunity to participate in research projects in the areas of medical error reduction, and to obtain research funding through a number of institutions such as the National Patient Safety Foundation. Increased interest in this subject through research would raise awareness of the importance of error reduction to high quality care, which would in turn benefit the entire medical center.

Senior Leadership

The commitment of the board of directors of this academic medical center is vital to the success of the actions detailed in this report. It is especially critical for a teaching hospital to remain at the forefront of technological innovation in quality patient care and research. No one would ever argue that an outdated, low-quality procedure be performed on patients just because "that's the way we have done it for 30 years." Conversely, if a new test were determined to improve patient outcomes by an impressive margin, physicians would be demanding access to the new therapy for their patients. Clearly, the senior leadership of this medical center now has the justification to take a new direction toward improving the quality of care by focusing the energies of the organization on patient safety, instituting the changes recommended in the

literature, and committing the resources necessary to reengineer the medication processes using the currently available technology. These processes must be redesigned to make it difficult to make errors. Even more importantly, the senior leadership must accept the responsibility for the results of the system that they design. The goal should be a world-class medication system that will benefit patients, staff and students for years to come.

Reference List

- American Society of Health-Systems Pharmacists (1996). Top-priority actions for preventing adverse drug events in hospitals: Recommendations of an expert panel. American Journal of Health-Systems Pharmacists, 53, 747-51.
- Bates, D. W., Cullen, D.J., Laird, N., Petersen, L. A., Small, S. D., Servi, D., Laffel, G., Sweitzer, B. J., Shea, B. F., Hallisey, R., et al. (1995). Incidence of adverse drug events and potential adverse drug events. Implications for prevention. Journal of the American Medical Association, 274(1), 29-34.
- Bates, D. W., Spell, N., Cullen, D.J., Burdick, E., Laird, N., & Petersen, L. A. (1997). The costs of adverse drug events in hospitalized patients. Journal of the American Medical Association, 277(4), 307-311.
- Bates, D. W., Leape, L. L., Cullen, D. J., Laird, N., Petersen, L. A., & Teich, J. M. (1998). Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. Journal of the American Medical Association, 280(15), 1311-1316.
- Bates, D.W. & Gawande, A.A. (2000). Error in medicine: what have we learned? Annals of Internal Medicine, 132(9), 763-767.
- Bates, D.W. (2000). Using information technology to reduce rates of medication errors in hospitals. British Medical Journal, 320, 788-791.
- Berwick, D. M. (1998, November). Taking action to improve safety: how to increase the odds of success. Keynote address at the 1998 Annenberg Conference, Rancho Mirage, CA. Retrieved February 1, 2000 from the World Wide Web at:
<http://www.annenberg.net/mederrors/html/keynote.html>

Berwick, D. M., & Leape, L. L. (1999). Reducing errors in medicine. British Medical Journal, 319, 136-137.

Brennan, T.A., Leape, L.L., & Laird, N. M. (1991). Incidence of adverse events and negligence in hospitalized patients: results from the Harvard Medical Practice Study I. The New England Journal of Medicine, 324, 370-376.

Casarett, D., & Helms, C. (1999). Systems errors versus physicians' errors: finding the balance in medical education. Academic Medicine, 74, 19-22.

CHCS II (2000). Commander's Guide for the Composite Health Care System II. CHCS II website. Retrieved 2 Mar 2001 from the World Wide Web at: <http://cba.ha.osd.mil/documents/documents-project.htm>.

Cullen, D.J., Bates, D.W., Small, S.D., Cooper, J.B., Nemestkal, A.R., & Leape, L.L. (1995). The incident reporting system does not detect adverse drug events: a problem for quality improvement. Joint Commission Journal on Quality Improvement, 21: 541-548.

Cullen, D.J., Sweitzer, B.J., Bates, D.W., Burdick, E., Edmondson, A., & Leape, L.L. (1997). Preventable adverse drug events in hospitalized patients: a comparative study of intensive care and general care units. Critical Care Medicine, 25(8):1289-97.

Donaldson, L. J., & Gray, J. A. (1998). Clinical governance: a quality duty for health organizations. Quality in Health Care, 7(Suppl), S37-S44.

Epocrates (2001). qRx clinical drug database for the Palm. Retrieved 2 Mar 2001 from the World Wide Web at: <http://www.epocrates.com>.

Healthcare Information and Management Systems Society (1996). Session 18: Implementing a physician order entry system: Perspectives from five physicians. 1996 HIMSS Proceedings, 1: 179-188.

Institute for Healthcare Quality (2001). Improving Safety In High Hazard Areas. Retrieved 2 Mar 2001 from the World Wide Web at:

<http://www.ihq.org/collaboratives/underway/QuIC/ci0301quic.asp>

Jha, A. K. (1998). Identifying adverse drug events: development of a computer-based monitor and comparison with chart review and stimulated voluntary report. Journal of the American Medical Informatics Association, 5(3):305-14.

Kohn, L., Corrigan, J., & Donaldson, M. (Eds.). (2000). To err is human: building a safer health system. Institute of Medicine report. National Academy Press, Washington, D.C.

Retrieved September 27, 2000 from the World Wide Web:

<http://www.nap.edu/books/0309068371/html>

Lazarou, J., Pomeranz, B. H., & Corey, P. N. (1998). Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. Journal of the American Medical Association, 279(15): 1200-1205.

Leape, L.L., Brennan, T.A., Laird, N., Lawthers, A.G., Localio, A.R., Barnes, B.A., Hebert, L., Newhouse, J.P., Weiler P.C., & Hiatt H. (1991). The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. New England Journal of Medicine, 324(6):377-84

Leape, L. L. (1994a). Error in medicine. Journal of the American Medical Association, 272 (23), 1851-1857.

Leape, L. L. (1994b, October.). Preventing adverse drug events. A presentation at the Understanding and Preventing Drug Misadventures Conference. Sponsored by American Society of Hospital Pharmacists Research and Education Foundation. Retrieved September 27, 2000 from the World Wide Web: <http://www.ashp.org/public/proad/mederror/plea.html>.

Leape, L.L., Bates, D.W., Cullen, D.J., Cooper, J., Demonaco, H.J., Gallivan, T., Halloway, R., Ives, J., Laird, N., et al. (1995) Systems analysis of adverse drug events. Journal of the American Medical Association, 274 (1), 35-43.

Leape, L.L., Woods, D.D., Hatlie, M.J., Kizer, K., Schroeder, S.A., & Lundberg, G.D. (1998). Promoting patient safety by preventing medical error. Journal of the American Medical Association, 280 (16), 1444-1447.

Leape, L.L., Cullen, D.J., Clapp, M.D., Burdick, E., Demonaco, H.J., Erickson, J.I., & Bates, D.W. (1999). Pharmacist participation on physician rounds and adverse drug events in the intensive care units. Journal of the American Medical Association, 282 (3), 267-270.

Leape, L.L., Kabcenell, A.I., Gandhi, T.K., Carver, P., Nolan, T.W., & Berwick, D.M. (2000). Reducing adverse drug events: lessons from a breakthrough series collaborative. Journal of Quality Improvement, 26(6), 321-331.

Massachusetts Hospital Association (2000). MHA best practice recommendations to reduce medication errors. Retrieved 27 Sep 2000, from the World Wide Web at: <http://www.mhalink.org/mcpme>.

Micromedex (2001). DRUGDEX[®] System, Drug & Pharmaceutical Information. Retrieved 28 Feb 2001 from the World Wide Web at: <http://www.micromedex.com/products/pd-drugdxsys.htm>.

National Patient Safety Foundation (2001). Request for Proposals for Research in Patient Safety. Retrieved 3 Mar 2001, from the World Wide Web at: <http://www.npsf.org/research.htm>.

Nightingale, P.G., Ada, D., Richards, N.T., and Peters, M. (2000). Implementation of rules based computerized bedside prescribing and administration intervention study. British Medical Journal, 320, 750-753.

Nolan, T.W. (2000). System changes to improve patient safety. British Medical Journal, 320, 771-773.

Pear, R. (2000, January 24). U.S. health officials reject plan to report medical mistakes. The New York Times, A14.

Pyxis (2001). PyxisConnect. Retrieved 2 Mar 2001 from the World Wide Web at:
<http://www.pyxis.com/html/products/pyxisConnect.asp>.

Reason, J. (1997). Managing the risks of organizational accidents. Burlington, VT: Ashgate Publishing Company.

Reason, J. (2000). Human error: models and management. British Medical Journal, 320, 768-770.

Robbins, S. P. (1998). Organizational Behavior (8th ed.). Upper Saddle River, NJ: Prentice-Hall.

Ryan, K.D. (1999). Driving fear out of the medication process so that improvement can occur. American Journal of Health-System Pharmacy, 56(17), 1765-1769.

Science Applications International Corporation (SAIC) website. Company Overview, 1987. Retrieved 2 Mar 2001 from the World Wide Web at:
<http://www.saic.com/about/timeline/1987.html>

Schiff, G.D. (1999). Computerized prescribing: steps to improve therapy. Hospital Practice, 34(8), 11-2, 17-8.

Sultz, H. A., & Young, K.M. (1999). Health care USA: understanding its organization and design (2nd ed.). Gaithersburg, Maryland: Aspen Publishers.

Thomas, E.J., Studdert, D.M., Burstin, H.R., Orav, E.J., Zeena, T., Williams, E.J., Howard, K.M., Weiler, P.C., & Brennan, T.A. (2000). Incidence and types of adverse events and negligent care in Utah and Colorado. Medical Care, 38(3), 261-71.

United States Pharmacopeia (2001). MedMARx, a national database for hospital medication error reporting. Retrieved 2 Mar 2001 from the World Wide Web at: <http://www.usp.org>.

Veterans' Administration (2001). Veterans' Health Information Systems and Technology Architecture. Retrieved 2 Mar 2001 from the World Wide Web at: www.va.gov/About_VA/Orgs/VHA/vista.htm.

Appendix A

List of Acronyms and Abbreviations

ACE	Angiotensin Converting Enzyme
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
CCU	Coronary Care Unit
CHCS(II)	Composite Health Care System (II)
CY	Calendar year
PCA	Patient-administered Analgesia
POE	Physician Order Entry
ICU	Intensive Care Unit
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
IM	Intramuscular
IM/IT	Information management/information technology
IV	Intravenous
IVPB	Intravenous piggy-back
MAR	Medication Administration Record
MICU	Medical Intensive Care Unit
NICU	Neonatal Intensive Care Unit
NSAID	Non-steroidal Anti-inflammatory Drug
PICU	Pediatric Intensive Care Unit
SICU	Surgical Intensive Care Unit
SPSS	Statistical Program for the Social Sciences
QuIC	Quality Interagency Coordination Task Force
USP	United States Pharmacopeia
VA	Veterans' Administration

Appendix B

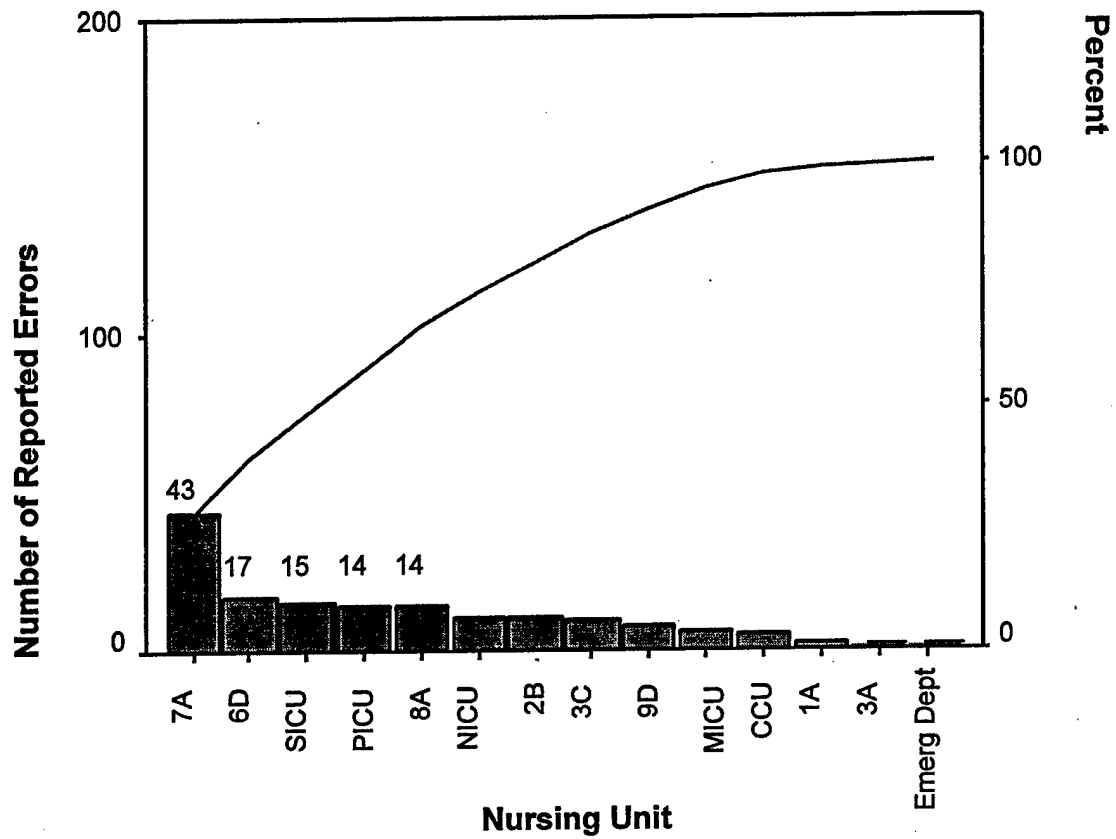


Figure B1 Medication Errors Reported by Unit

Unit	Reported Errors	Occupied Bed Days	Expected Errors (E)	Difference	Difference ²	Difference ² /E
6D	17	2807	6.12	-10.88	118.40	19.35
7A	43	10916	23.80	-19.20	368.81	15.50
8A	14	4925	10.74	-3.26	10.65	0.99
2B	10	6834	14.90	4.90	23.98	1.61
3C	10	6959	15.17	5.17	26.73	1.76
1A	2	2638	5.75	3.75	14.07	2.45
9D	8	12630	27.53	19.53	381.50	13.86
Total	104	47709	104	0	944.13	55.52

The expected number of errors (column 4) is computed by multiplying the mean number of errors per occupied bed day (.00218) by the number of bed days.

$df = 6$

$F(p=.005) = 18.55$.

Since $55.52 > 18.55$, $p < .005$

Figure B2. Calculation of Goodness-of-Fit Test for Medication Errors by non-ICU Units,
Adjusted for Occupied Bed Days for calendar year 2000

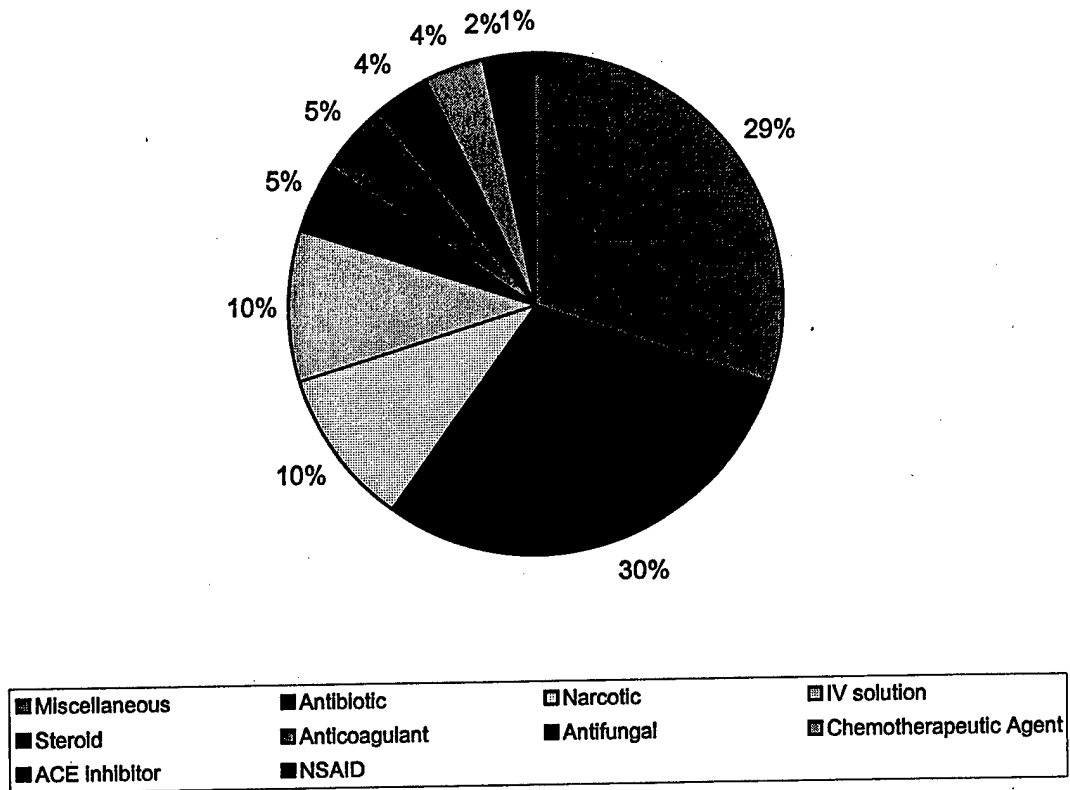


Figure B3. Class of Medication involved in Reported Errors

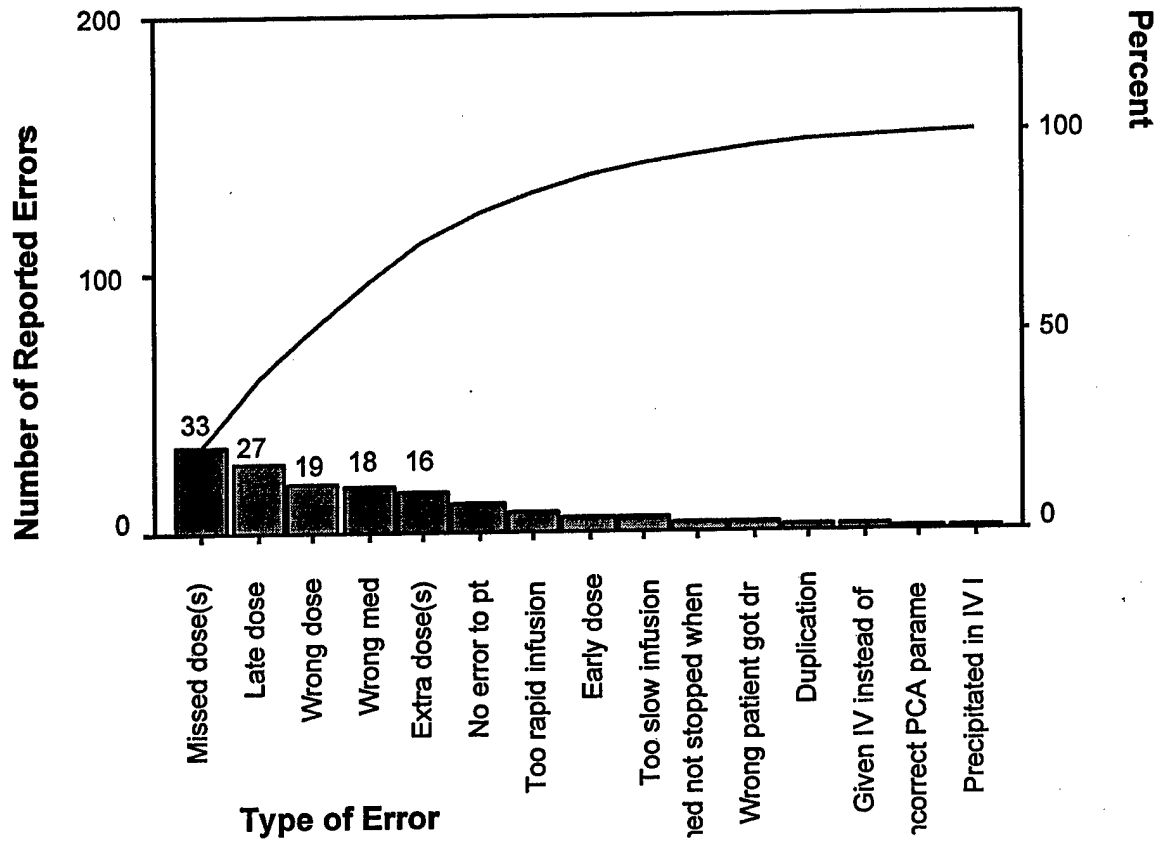


Figure B4. Types of Reported Medication Errors

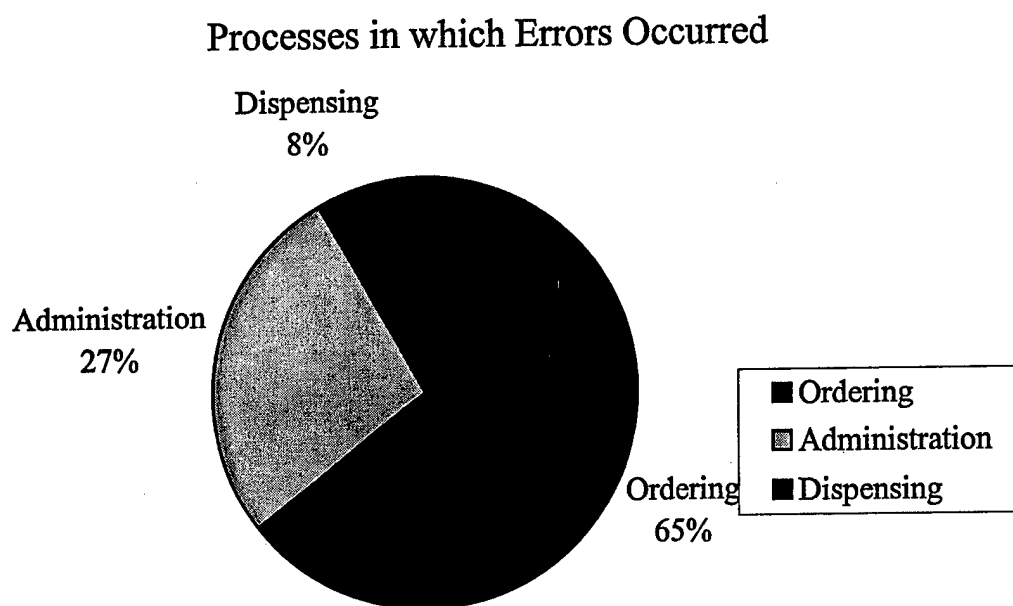


Figure B5. Processes in which Reported Errors Occurred

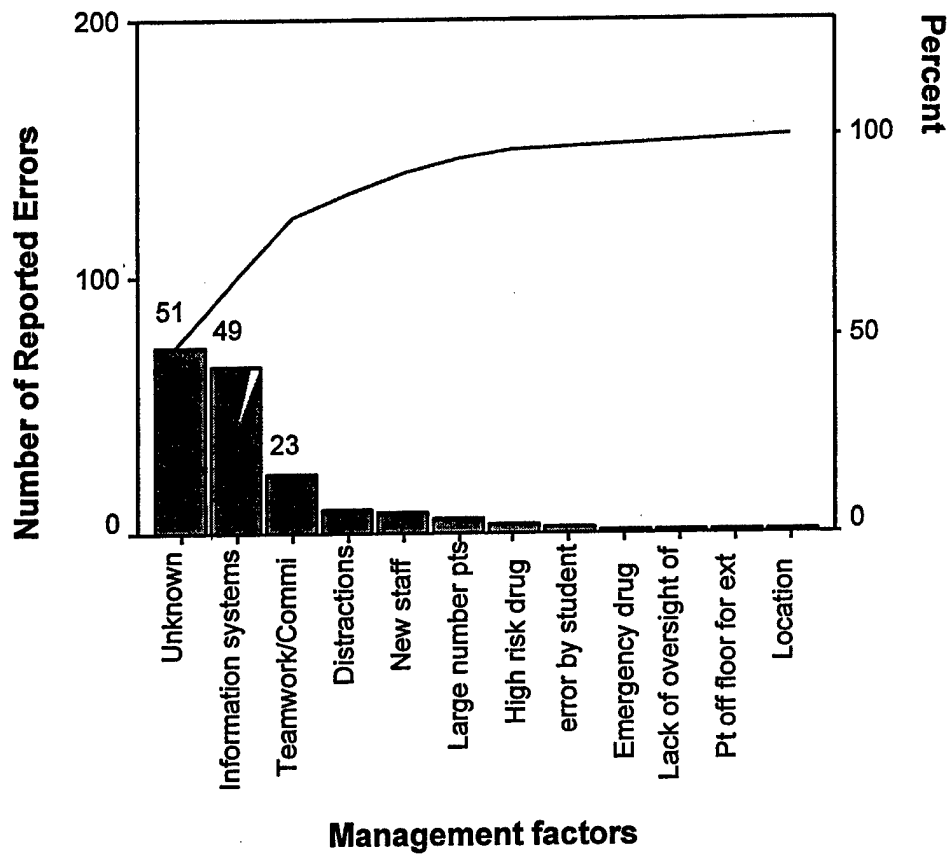
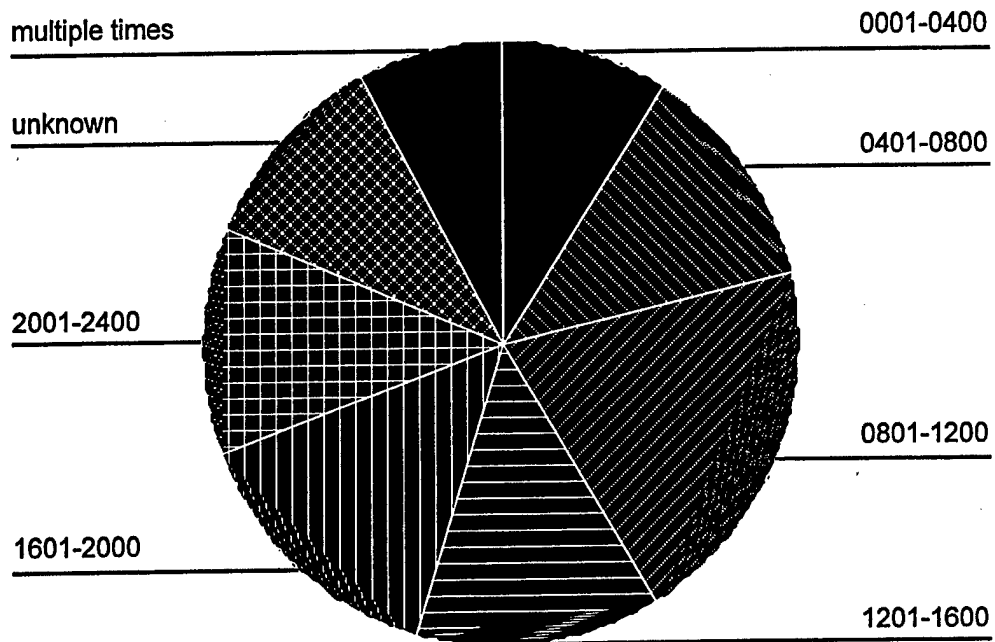


Figure B6. Management Factors in Reported Errors



$p > .05$, results not significant

Figure B7. Times of Reported Medication Errors

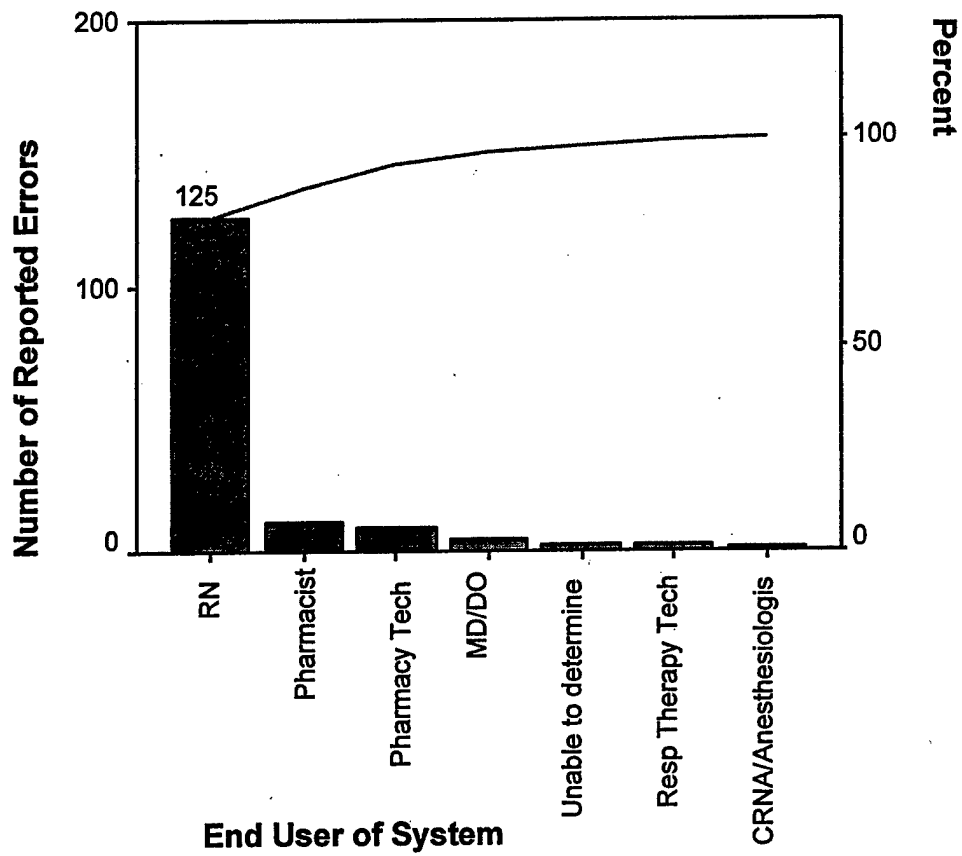


Figure B8. End User of the Medication System

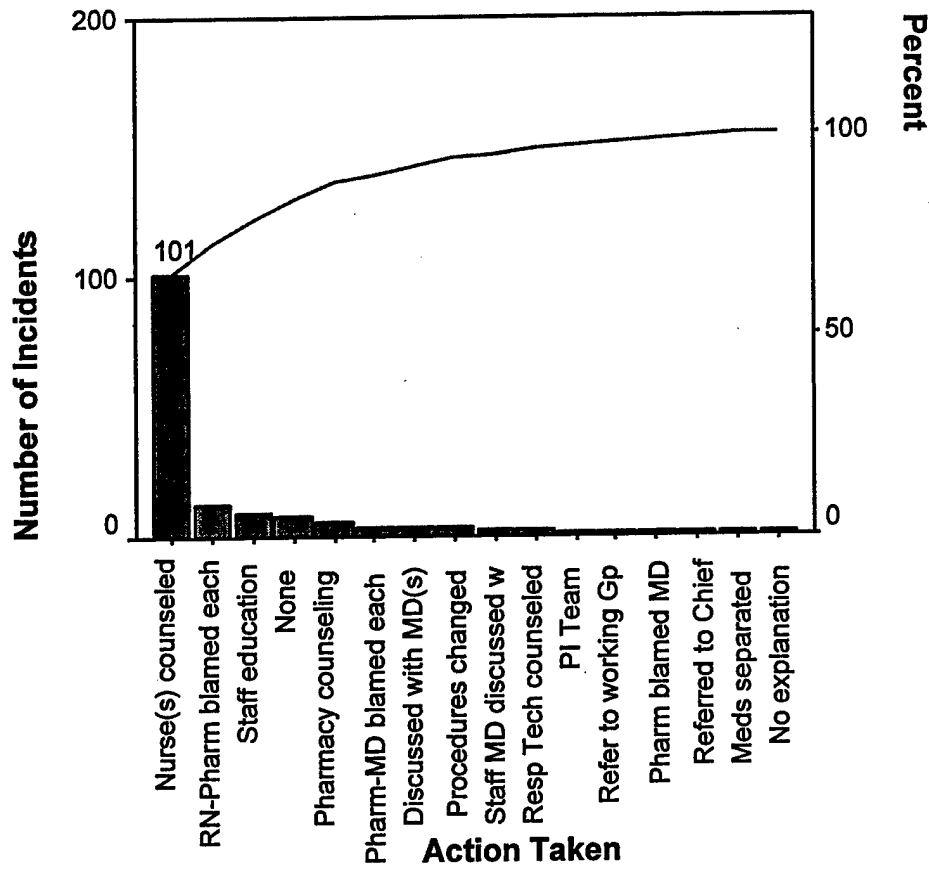


Figure B9. Actions Taken as a Result of Medication Errors

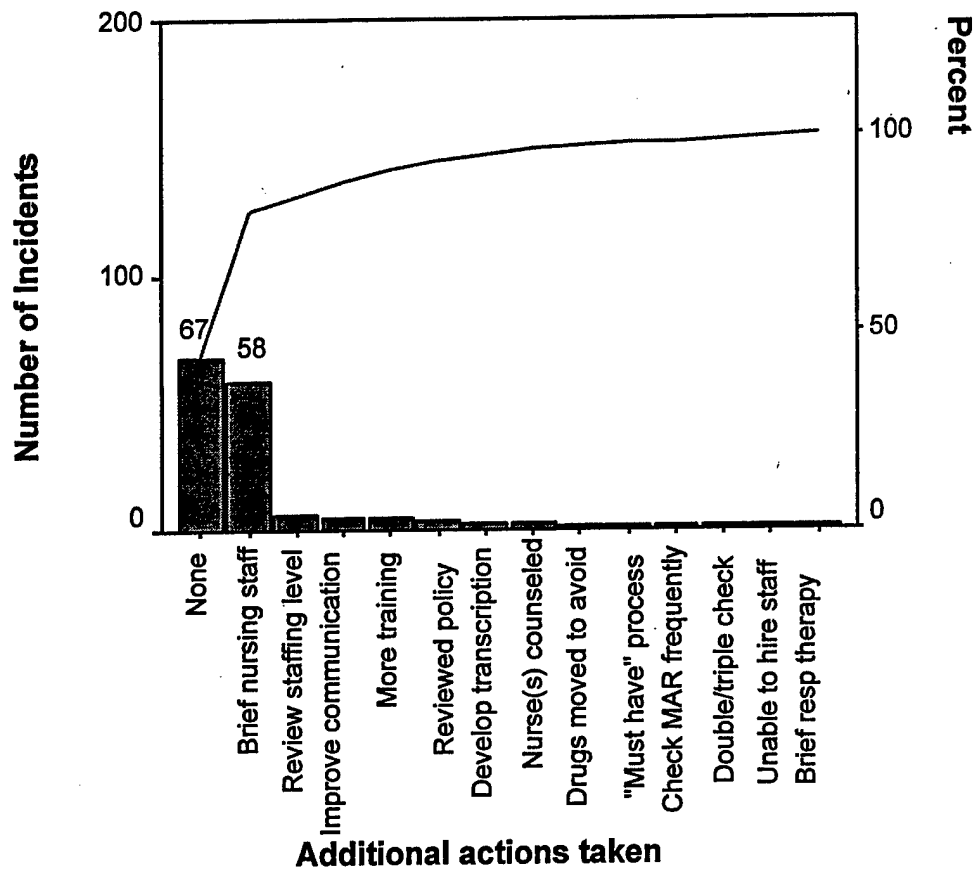


Figure B10. Additional Actions Taken as a Result of Medication Errors

Appendix C

Medications included in "Miscellaneous" Class:

	Number of Errors		Number of Errors
Multiple medications (not specified)	4		
Zantac	3		
Lopressor	3		
Magnesium sulfate	2		
Albuterol	2		
Acyclovir	2		
Sodium phosphate	2		
Digoxin	1	Amlodipine	1
Marinol	1	Chorthiazide IV	1
Cyclosporine	1	Losartan	1
Oxytocin	1	Aspirin	1
Flovent	1	Potassium phosphate	1
Prostaglandin E1	1	IV immunoglobulin	1
Nembutal	1	Clonidine	1
Insulin	1	Candesartan	1
Leucovorin	1	Prostin	1
Versed	1	Dulcolax	1
Dopamine	1	Hydrochlorothiazide	1
Labetolol	1	Dilantin	1
Cerivastatin	1	Ropivacaine	1
Epidural (unspecified)	1	Mesna	1
Benadryl	1	Ritalin	1
Reglan	1		

Appendix D

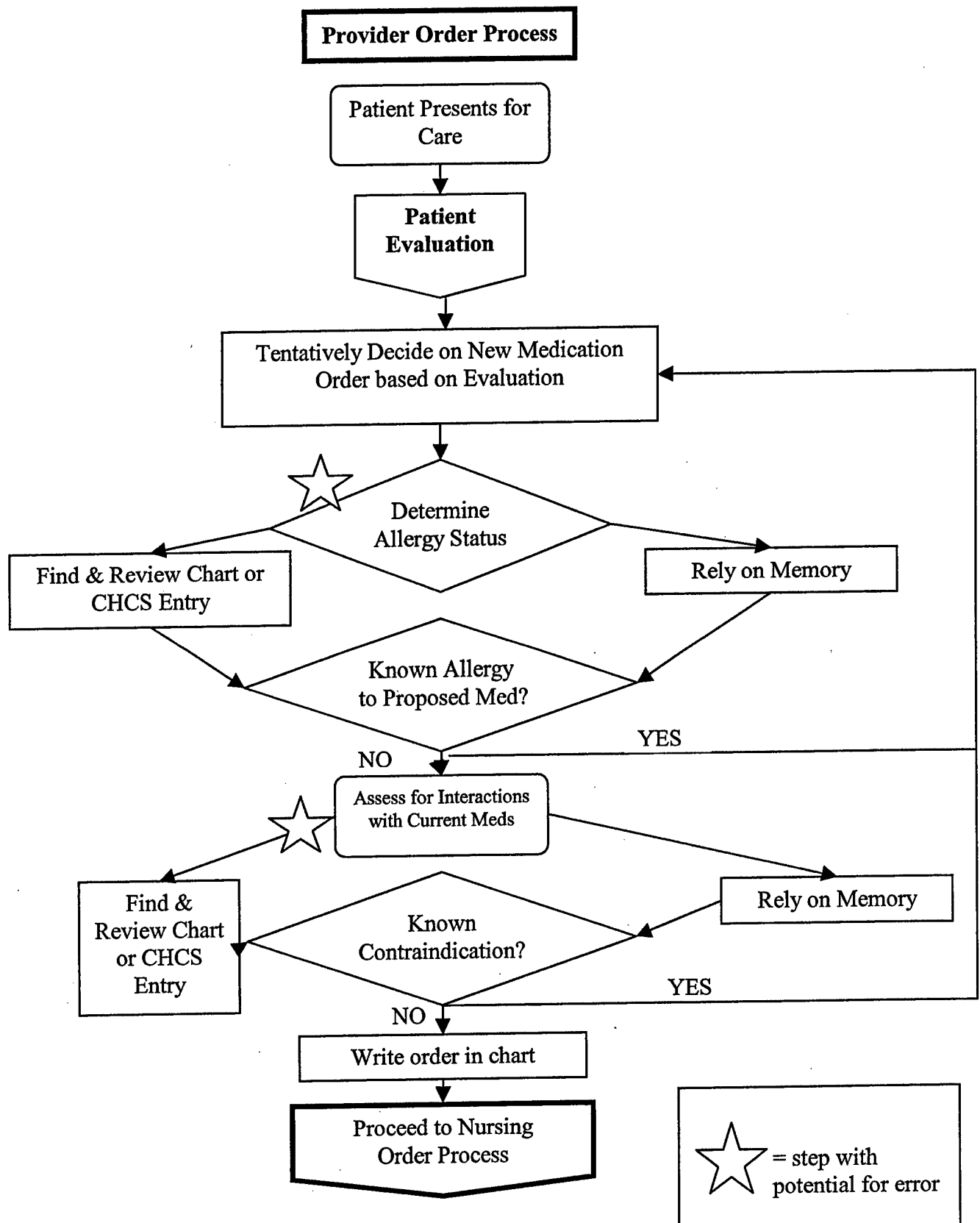


Figure D1. Provider Order Process

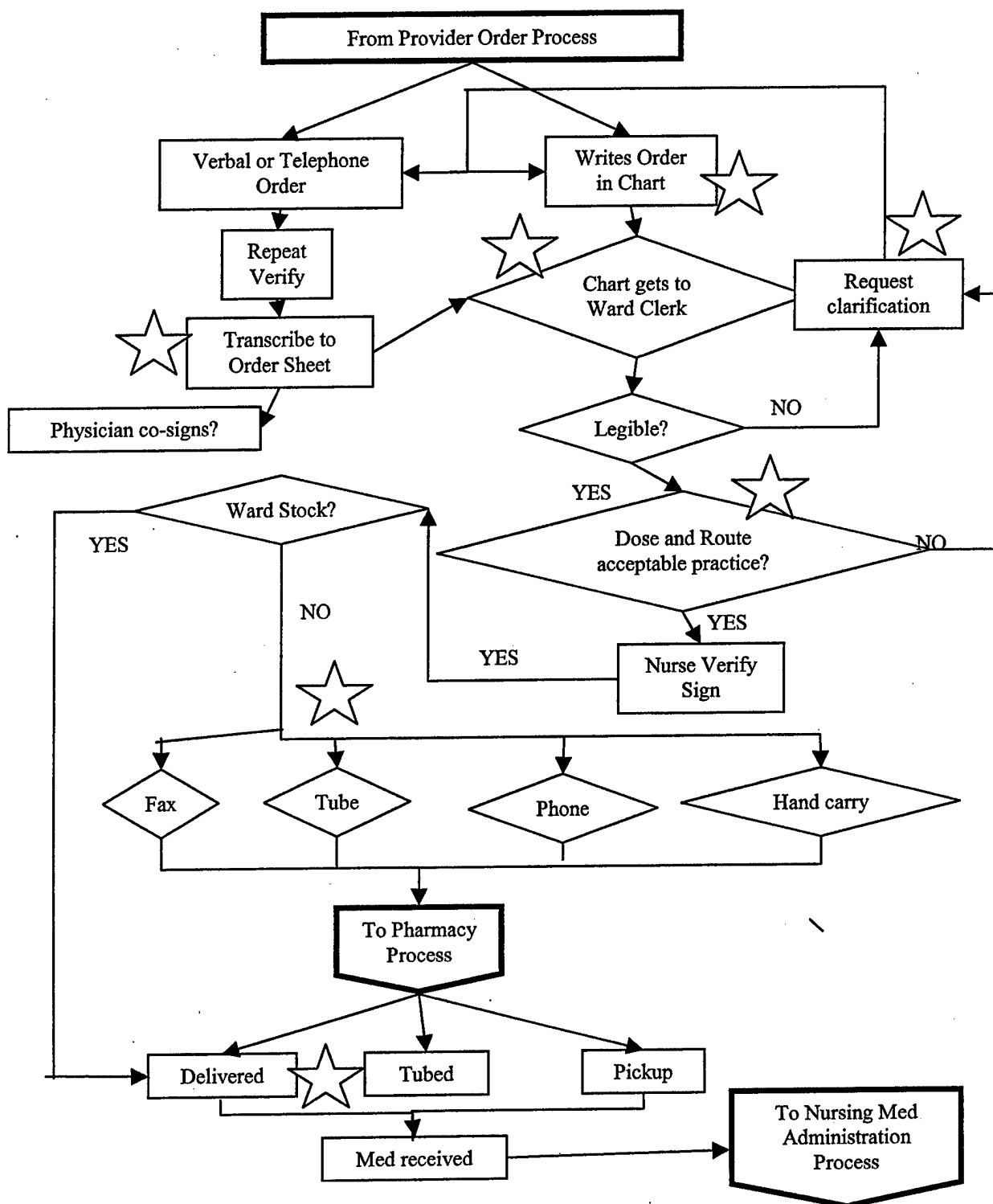


Figure D2. Nursing Order Process

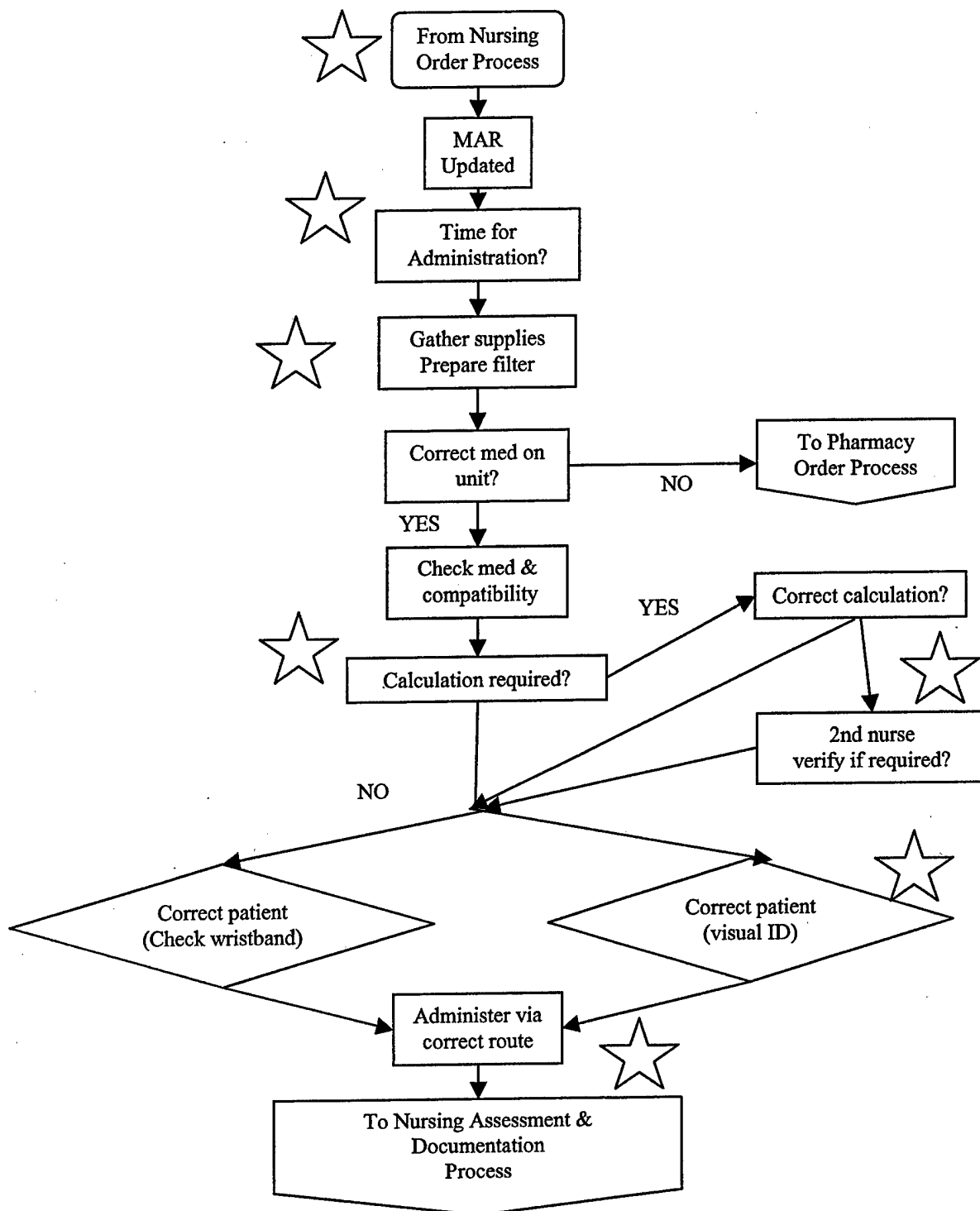


Figure D3. Nursing Medication Administration Process

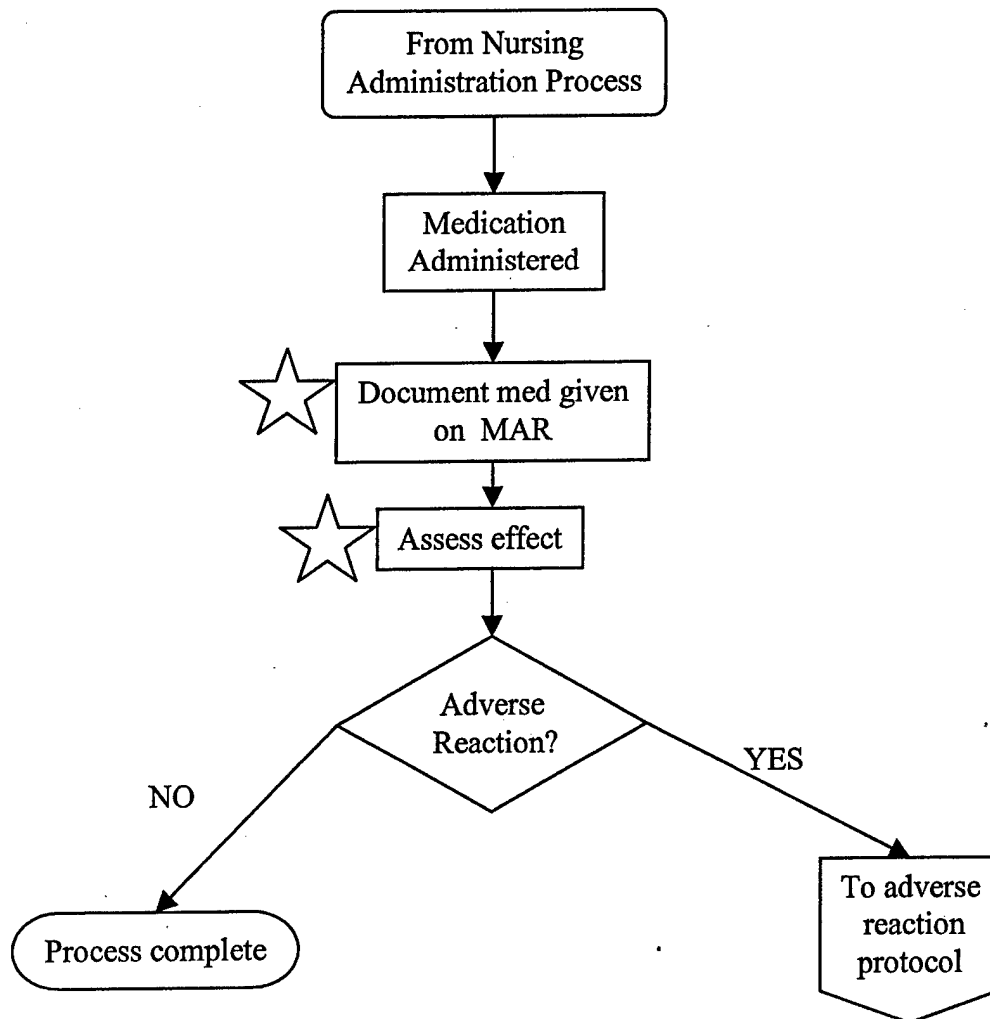


Figure D4. Nursing Assessment and Documentation Process

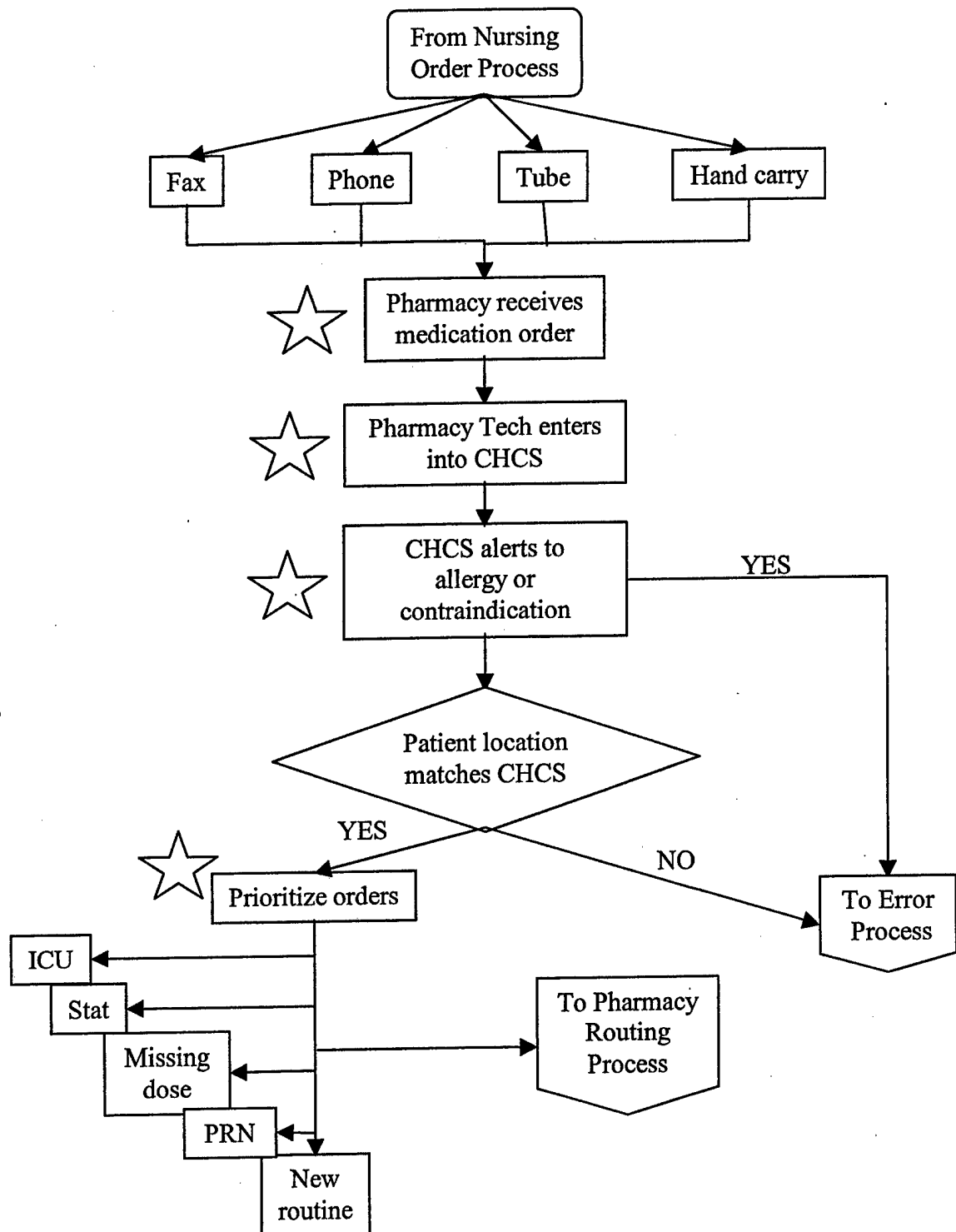


Figure D5. Pharmacy Process I

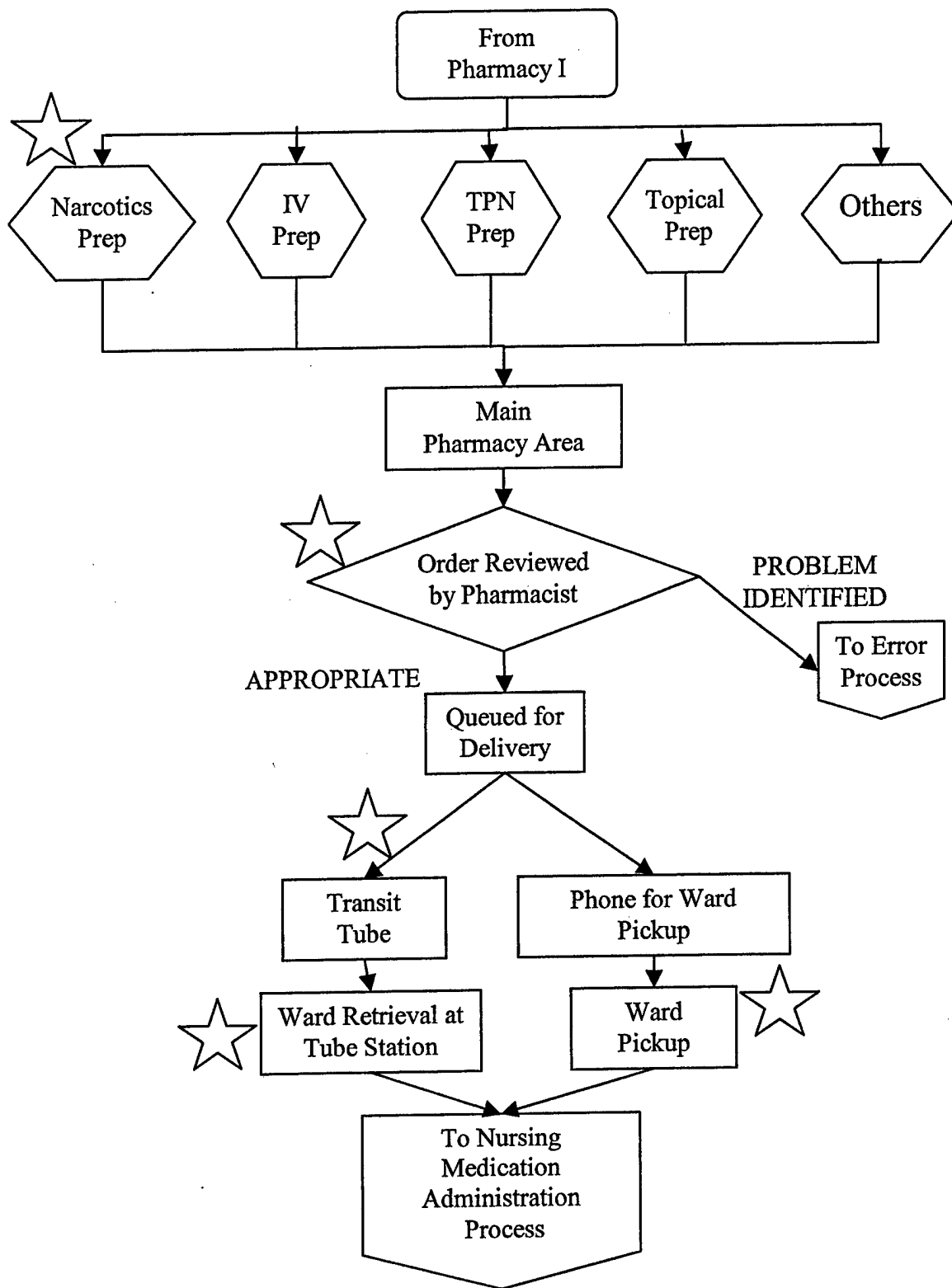


Figure D6. Pharmacy Process II

Appendix E

Example of Problems in Handwritten Orders

ORDERS - (SIGN ALL ORDERS)		
The Date and Time, Sign, and Cross Out the Unused Lines		
DATE OF ORDER	22 Aug 00	TIME 1715
<ol style="list-style-type: none"> ① Dicloxacillin ② Dicloxacillin ③ Start Levofloxacin 500mg po Q6 AM on 23 Aug 00. ④ Chem 10+mg ⑤ 1830-1900 Allright, imp ⑥ Clonidine 5mg Q6 AM ⑦ po QHS PRN sleep 		
DATE OF ORDER	22 Aug 00	TIME 2030
<ol style="list-style-type: none"> ① Neupogen 1000 po QD 		

DATE OF ORDER	10 Sept 00	TIME 2345	Notes
<ol style="list-style-type: none"> ① 1gm Tylenol po x 1 ② 180mg Gentamicin IV bolus ③ 140mg Gent IV q 8 ④ Cefixime 500mg ⑤ 1/2 Gent bolus 128 ⑥ Ampicillin 2g q 6 			
			J. Jones 15- [Signature]

Figure. Two examples of poor handwriting and confusing orders. In top example, Levofloxacin 500 mg PO q 6 AM was interpreted to mean every 6 hrs starting in the am on 23 Aug, not once a day at 6 am. In the lower example, 130 mg Gent (amycin) IV q 8^o has been changed to 140 mg, but nurse and pharmacist misinterpreted the order.

Appendix F.

Figure F. Veterans Administration Incident Report Form

Appendix G

Priority	Action	Benefit	Stage of Process
Complete	Remove concentrated KCl from all nursing units	Constraint to avoid overdose	Administration
Complete	Continue 24 hour/day availability of a pharmacist on call	Expert drug information source available to clinicians	Ordering and Administration
Complete	Program unit fax machines to automatically label faxes with originating unit	Pharmacy knows originating unit	Pharmacy Routing
Complete	Assign Critical Care Pharmacist to ICUs to provide information to medical and nursing staff	Expert drug information source available to clinicians	Ordering and Administration
Complete	Use pharmacy-based IV admixture systems	Reduces calculation by nurses	Dispensing
Initiated	Implement telephone system for reporting "near misses"	Easier reporting	Reporting
Initiated	Maintain/expand unit dose distribution system for all non-emergency medications	Reduces calculation	Dispensing and Administration
Initiated	Continue participation in IHI collaborative for reduction of medical errors	Access to real-world best practices	All stages

Figure G1. Matrix showing Error Prevention Actions Completed or Initiated

Priority	Action	Benefit	Stage of Process
1	Promote a systems-oriented approach to medication error reduction throughout the organization	Foundation for all other cultural changes	Organizational Culture
2	Promote a non-punitive atmosphere for reporting of errors which values the sharing of information about the causes of errors and strategies for prevention	Foundation for all other cultural changes	Organizational Culture Reporting
3	Redesign incident reporting form to identify patient outcomes, reduce narrative required, & use check boxes to increase reporting of systems issues	Under-reporting of medication errors	Reporting
4	Obtain Pyxis-Connect system to send orders to Pharmacy	Pharmacy and nursing staff aware of order status, decreased phone calls and distractions for Pharmacy	Ordering Dispensing
5	Develop special procedures for high-risk drugs	Minimize adverse impact of poor handwriting. Standard doses decrease opportunity for dosing error	Ordering Dispensing Administration
6	Standardize & simplify medication processes	Fewer steps in processes reduce errors	All stages
7	Eliminate problem-prone ordering practices, such as use of "QD" for daily and "U" for units	Minimize adverse impact of handwritten orders	Ordering
8	Expand Surgery Pharmacy to allow use by ICU for drugs requiring nurse signature (i.e. narcotics)	Minimize time nurses have to leave ICU patients to obtain medications	Administration
9	Institute pharmacy/medication process and CHCS orientation/training for all newly assigned nursing staff	Improved knowledge of medication processes and information resources	All stages
10	Institute pharmacy/medication process and computer system orientation/training for all newly assigned medical staff	Improved knowledge of medication processes and information resources	All stages
11	Employ MedMARx, national, standardized database for reporting and tracking medication errors	Benchmarking and best practices	Reporting
12	Upgrade computer skills training for nursing service personnel and obtain handheld devices for ePocrates	Improved knowledge of medications and ability to use information resources	All stages

Figure G2. Matrix showing Recommendations for Actions over Short Term (12-24 months)

Priority	Action	Benefit	Stage of Process
1	Obtain and deploy Physician Inpatient Order Entry system	Foundation of automated systems approach to medication error reduction	All stages
2	Purchase bar-coding and scanning system for all inpatient medications	Ensures right patient gets the right medicine at the right time. Generates computerized MAR	Administration Documentation
3	Review of all discharge summaries by pharmacist for ADRs/medication errors	Improved knowledge of root causes of medication errors and ADRs	Reporting
4	Robotic system for filling prescriptions-free pharmacists for consultative patient care roles	Expert drug information source available to clinicians. Improved pharmacy efficiency	Ordering Dispensing Administration
5	Incorporation of national or locally developed evidence-based guidelines into POE systems	Reduce reliance on memory Increase standardization	Ordering Administration
6	Computer-based ADR surveillance system to replace incident reporting	Improved knowledge of causes of medication errors and ADRs	Reporting
7	"Flatten" organization to eliminate unnecessary hierarchical structures	Improved teamwork And communication	All stages
8	Revise master facility plan to relocate nursing units to more easily accessible area/redesign to improve delivery systems	Improved efficiency	Dispensing Administration
Additional Actions	Participate in patient-safety research funded through various agencies such as the National Patient Safety Foundation	Advance knowledge in field of error prevention	Research All stages

Figure G3. Matrix showing Recommendations for Actions over Long Term (>24 months) and Additional Actions for Consideration